JMCP ■ Journal of Managed Care & Specialty Pharmacy ■ October 2017 ■ Supplement ■ Vol. 23, No. 10-a

Journal of Managed Care & Specialty Pharmacy®

Supplement ■ Volume 23 ■ Number 10-a ■ October 2017

Meeting Abstracts

Academy of Managed Care Pharmacy Nexus 2017

Dallas, Texas
October 16-19, 2017

JMCP Journal of Managed Care & Specialty Pharmacy®
Previously published as JMCP, the Journal of Managed Care Pharmacy®
A Peer-Reviewed Journal of the Academy of Managed Care Pharmacy ■ www.jmcp.org ■ www.amcp.org
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JMCP

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POSTMASTER: Send address changes to *JMCP*, 675 North Washington St., Suite 220, Alexandria, VA 22314.

AMCP Abstracts Program

The AMCP Abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice through publication in AMCP's *Journal of Managed Care & Specialty Pharmacy (JMCP)*. Abstracts that have been reviewed are published in the *JMCP* Meeting Abstracts supplement.

Poster presentations for AMCP Nexus 2017 are scheduled for **Wednesday, October 18, from 12:00 pm to 2:45 pm**. For each poster, at least 1 author is available during the poster presentations to discuss findings. Posters will also be displayed on **Tuesday, October 17, from 4:15 pm to 6:15 pm**, during the opening night reception in the Exchange.

The AMCP Nexus 2017 meeting in Dallas, Texas, is expected to attract more than 2,400 managed care pharmacists and other health care professionals who manage and evaluate drug therapies, develop and manage networks, and work with medical managers and information specialists to improve the care of all individuals enrolled in managed care programs.

Abstracts were submitted in the following categories:

Research Report: Describes completed original research on managed care pharmacy services or health care interventions. Examples include (but are not limited to) observational studies using administrative claims, reports of the effect of unique benefit design strategies, and analyses of the effects of innovative administrative or clinical programs.

Economic Model: Describes models that predict the effect of various benefit design or clinical decisions on a population. For example, an economic model could be used to predict the budget impact of a new pharmaceutical product on a health care system.

Solving Problems in Managed Care: Describes a problem or issue that exists in managed care; the goal for the intervention or practice; and the intervention or best practice implemented to address a specific issue (e.g., introduce a needed change, develop and implement a new system or program, plan and organize an administrative function, or solve other types of problems in managed care settings). In this category, abstracts describe what was observed after or when the intervention or best practice was implemented and provide a general overview of subjective and objective findings and recommendations for future research. Procedures for abstracts in this category are not as rigorous as those for a research report when describing the outcomes of an intervention and do not contain hypothesis testing, thus, they do not have firm conclusions.

Abstract Review Process

Ninety reviewers and 3 *JMCP* editorial reviewers were involved in the abstract review process for AMCP Nexus 2017. Each abstract (with author name and affiliation blinded) was reviewed by reviewers and scored using a 1-5 scale on the following 5 criteria (15 rating scores per abstract) used by *JMCP* to evaluate manuscripts for publication

• Relevance • Originality • Quality • Bias • Clarity

Each of the reviewers also made an independent accept/reject recommendation. The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a *JMCP* editorial reviewer, who made an accept/reject decision. These decisions were further reviewed by the *JMCP* editor-in-chief to ensure consistency in decision making. The mean rating scores were used to award Platinum, Gold, Silver, and Bronze medals for the best abstracts submitted. The abstract reviewers for AMCP Nexus 2017 were as follows:

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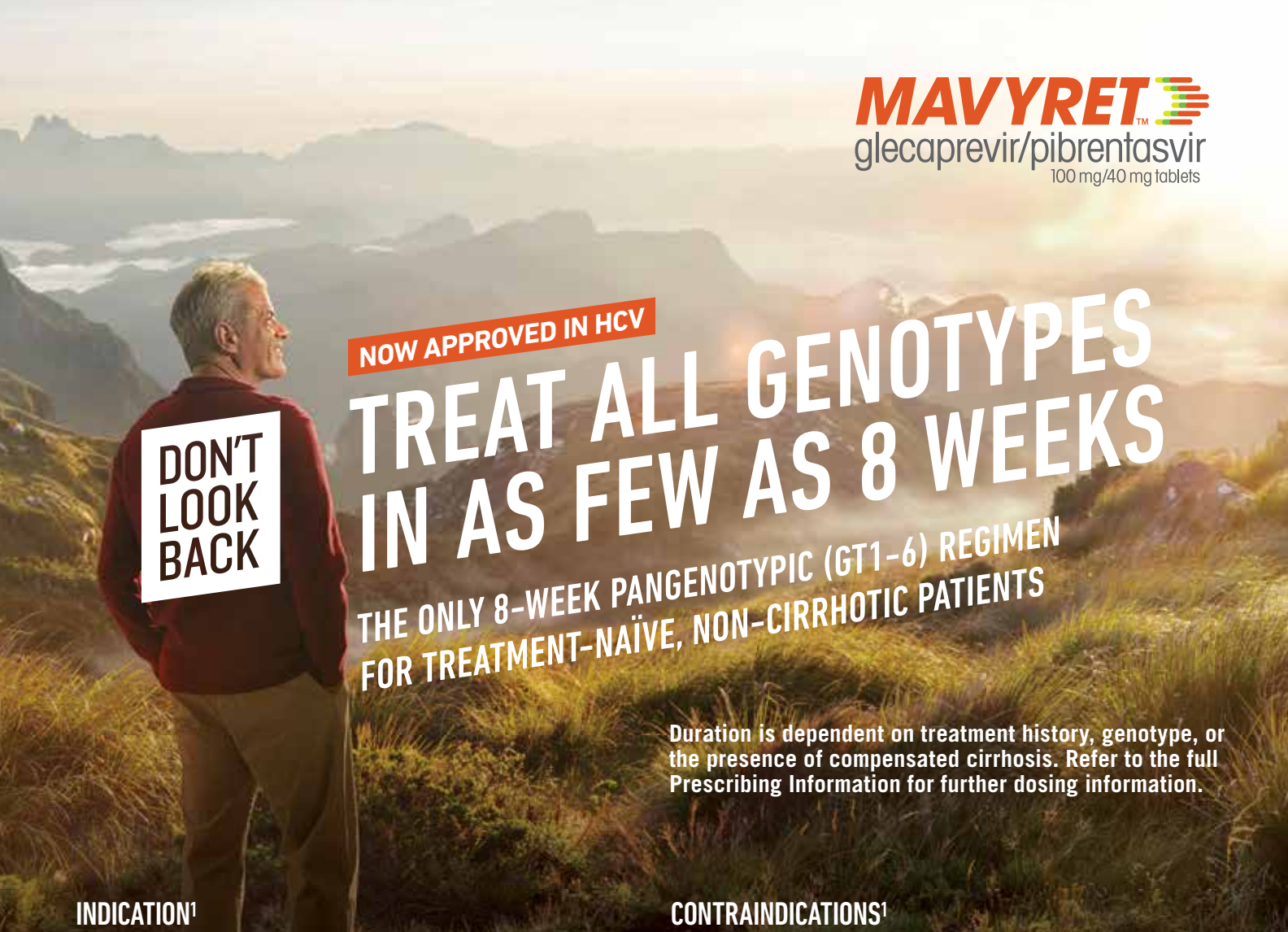
MAVYRET™
glecaprevir/pibrentasvir
100 mg/40 mg tablets



NOW APPROVED IN HCV

TREAT ALL GENOTYPES IN AS FEW AS 8 WEEKS

THE ONLY 8-WEEK PANGENOTYPIC (GT1-6) REGIMEN FOR TREATMENT-NAÏVE, NON-CIRRHOTIC PATIENTS

Duration is dependent on treatment history, genotype, or the presence of compensated cirrhosis. Refer to the full Prescribing Information for further dosing information.

INDICATION[1]

MAVYRET™ (glecaprevir and pibrentasvir) tablets are indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

IMPORTANT SAFETY INFORMATION[1]

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

CONTRAINDICATIONS[1]

MAVYRET is contraindicated:

- In patients with severe hepatic impairment (Child-Pugh C)
- With the following drugs: atazanavir or rifampin

WARNINGS AND PRECAUTIONS[1]

Risk of Reduced Therapeutic Effect Due to Concomitant Use of MAVYRET with Carbamazepine, Efavirenz-containing Regimens, or St. John's Wort

- Carbamazepine, efavirenz, and St. John's Wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

ADVERSE REACTIONS[1]

Most common adverse reactions observed with MAVYRET:

- >10% of subjects: headache and fatigue
- ≥5% of subjects: headache, fatigue, and nausea

Please see following pages for a brief summary of the full Prescribing Information.

Reference: 1. MAVYRET [package insert]. North Chicago, IL: AbbVie Inc.; 2017.

MAVYRET™ (glecaprevir and pibrentasvir) tablets, for oral use

PROFESSIONAL BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

MAVYRET is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

CONTRAINDICATIONS

MAVYRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C) *[see Use in Specific Populations]*.

MAVYRET is contraindicated with atazanavir or rifampin *[see Drug Interaction]*.

WARNINGS AND PRECAUTIONS

Risk of Hepatitis B Virus Reactivation in Patients Coinfected with HCV and HBV

Hepatitis B virus (HBV) reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals, and who were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure and death. Cases have been reported in patients who are HBsAg positive and also in patients with serologic evidence of resolved HBV infection (i.e., HBsAg negative and anti-HBc positive). HBV reactivation has also been reported in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV direct-acting antivirals may be increased in these patients.

HBV reactivation is characterized as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level. In patients with resolved HBV infection reappearance of HBsAg can occur. Reactivation of HBV replication may be accompanied by hepatitis, i.e., increase in aminotransferase levels and, in severe cases, increases in bilirubin levels, liver failure, and death can occur.

Test all patients for evidence of current or prior HBV infection by measuring HBsAg and anti- HBc before initiating HCV treatment with MAVYRET. In patients with serologic evidence of HBV infection, monitor for clinical and laboratory signs of hepatitis flare or HBV reactivation during HCV treatment with MAVYRET and during post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Risk of Reduced Therapeutic Effect Due to Concomitant Use of MAVYRET with Carbamazepine, Efavirenz Containing Regimens, or St. John's Wort

Carbamazepine, efavirenz, and St. John's wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of MAVYRET cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Overall Adverse Reactions in HCV-Infected Adults Without Cirrhosis or With Compensated Cirrhosis (Child-Pugh A)

The adverse reactions data for MAVYRET in subjects without cirrhosis or with compensated cirrhosis (Child-Pugh A) were derived from nine Phase 2 and 3 trials which evaluated approximately 2,300 subjects infected with genotype 1, 2, 3, 4, 5, or 6 HCV who received MAVYRET for 8, 12 or 16 weeks.

The overall proportion of subjects who permanently discontinued treatment due to adverse reactions was 0.1% for subjects who received MAVYRET for 8, 12 or 16 weeks.

The most common adverse reactions, all grades, observed in greater than or equal to 5% of subjects receiving 8, 12, or 16 weeks of treatment with MAVYRET were headache (13%), fatigue (11%), and nausea (8%). In subjects receiving MAVYRET who experienced adverse reactions, 80% had an adverse reaction of mild severity (Grade 1). One subject experienced a serious adverse reaction.

Adverse reactions (type and severity) were similar for subjects receiving MAVYRET for 8, 12 or 16 weeks. The type and severity of adverse reactions in subjects with compensated cirrhosis (Child-Pugh A) were comparable to those seen in subjects without cirrhosis.

Adverse Reactions in HCV-Infected Adults treated with MAVYRET in Controlled Trials

ENDURANCE-2

Among 302 treatment-naïve or PRS treatment-experienced, HCV genotype 2 infected adults enrolled in ENDURANCE-2, adverse reactions (all intensity) occurring in at least 5% of subjects treated with MAVYRET for 12 weeks are presented in Table 1. In subjects treated with MAVYRET for 12 weeks, 32% reported an adverse reaction, of which 98% had adverse reactions of mild or moderate severity. No subjects treated with MAVYRET or placebo in ENDURANCE-2 permanently discontinued treatment due to an adverse drug reaction.

Table 1. Adverse Reactions Reported in ≥5% of Treatment-Naïve and PRS-Experienced Adults Without Cirrhosis Receiving MAVYRET for 12 Weeks in ENDURANCE-2

Adverse Reaction	MAVYRET 12 Weeks (N = 202) %	Placebo 12 Weeks (N = 100) %
Headache	9	6
Nausea	6	2
Diarrhea	5	2

ENDURANCE-3

Among 505 treatment-naïve, HCV genotype 3 infected adults without cirrhosis enrolled in ENDURANCE-3, adverse reactions (all intensity) occurring in at least 5% of subjects treated with MAVYRET for 8 or 12 weeks are presented in Table 2. In subjects treated with MAVYRET, 45% reported an adverse reaction, of which 99% had adverse reactions of mild or moderate severity. The proportion of subjects who permanently discontinued treatment due to adverse reactions was 0%, < 1% and 1% for the MAVYRET 8 week arm, MAVYRET 12 week arm and DCV + SOF arm, respectively.

Table 2. Adverse Reactions Reported in ≥5% of Treatment-Naïve Adults Without Cirrhosis Receiving MAVYRET for 8 Weeks or 12 Weeks in ENDURANCE-3

Adverse Reaction	MAVYRET* 8 Weeks (N = 157) %	MAVYRET 12 Weeks (N = 233) %	DCV[1] + SOF[2] 12 Weeks (N = 115) %
Headache	16	17	15
Fatigue	11	14	12
Nausea	9	12	12
Diarrhea	7	3	3

[1] DCV=daclatasvir
[2] SOF=sofosbuvir
* The 8 week arm was a non-randomized treatment arm.

Adverse Reactions in HCV-Infected Adults with Severe Renal Impairment Including Subjects on Dialysis

The safety of MAVYRET in subjects with chronic kidney disease (Stage 4 or Stage 5 including subjects on dialysis) with genotypes 1, 2, 3, 4, 5 or 6 chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) was assessed in 104 subjects (EXPEDITION-4) who received MAVYRET for 12 weeks. The most common adverse reactions observed in greater than or equal to 5% of subjects receiving 12 weeks of treatment with MAVYRET were pruritus (17%), fatigue (12%), nausea (9%), asthenia (7%), and headache (6%). In subjects treated with MAVYRET who reported an adverse reaction, 90% had adverse reactions of mild or moderate severity (Grade 1 or 2). The proportion of subjects who permanently discontinued treatment due to adverse reactions was 2%.

Laboratory Abnormalities

Serum bilirubin elevations

Elevations of total bilirubin at least 2 times the upper limit of normal occurred in 3.5% of subjects treated with MAVYRET versus 0% in placebo; these elevations were observed in 1.2% of subjects across the Phase 2 and 3 trials. MAVYRET inhibits OATP1B1/3 and is a weak inhibitor of UGT1A1 and may have the potential to impact bilirubin transport and metabolism, including direct and indirect bilirubin. No subjects experienced jaundice and total bilirubin levels decreased after completing MAVYRET.

DRUG INTERACTIONS

Mechanisms for the Potential Effect of MAVYRET on Other Drugs

Glecaprevir and pibrentasvir are inhibitors of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide (OATP) 1B1/3. Coadministration with MAVYRET may increase plasma concentration of drugs that are substrates of P-gp, BCRP, OATP1B1 or OATP1B3. Glecaprevir and pibrentasvir are weak inhibitors of cytochrome P450 (CYP) 3A, CYP1A2, and uridine glucuronosyltransferase (UGT) 1A1.

Mechanisms for the Potential Effect of Other Drugs on MAVYRET

Glecaprevir and pibrentasvir are substrates of P-gp and/or BCRP. Glecaprevir is a substrate of OATP1B1/3. Coadministration of MAVYRET with drugs that inhibit hepatic P-gp, BCRP, or OATP1B1/3 may increase the plasma concentrations of glecaprevir and/or pibrentasvir.

Coadministration of MAVYRET with drugs that induce P-gp/CYP3A may decrease glecaprevir and pibrentasvir plasma concentrations.

Carbamazepine, efavirenz, and St. John's wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended *[see Warnings and Precautions]*.

Established and Other Potential Drug Interactions

Table 3 provides the effect of MAVYRET on concentrations of coadministered drugs and the effect of coadministered drugs on glecaprevir and pibrentasvir *[see Contraindications]*.

Table 3. Potentially Significant Drug Interactions Identified in Drug Interaction Studies

Concomitant Drug Class: Drug Name	Effect on Concentration	Clinical Comments
Antiarrhythmics:		
Digoxin	↑ digoxin	Measure serum digoxin concentrations before initiating MAVYRET. Reduce digoxin concentrations by decreasing the dose by approximately 50% or by modifying the dosing frequency and continue monitoring.
Anticoagulants:		
Dabigatran etexilate	↑ dabigatran	If MAVYRET and dabigatran etexilate are coadministered, refer to the dabigatran etexilate prescribing information for dabigatran etexilate dose modifications in combination with P-gp inhibitors in the setting of renal impairment.
Anticonvulsants:		
Carbamazepine	↓ glecaprevir ↓ pibrentasvir	Coadministration may lead to reduced therapeutic effect of MAVYRET and is not recommended.
Antimycobacterials:		
Rifampin	↓ glecaprevir ↓ pibrentasvir	Coadministration is contraindicated because of potential loss of therapeutic effect *[see Contraindications]*.
Ethinyl Estradiol-Containing Products:		
Ethinyl estradiol-containing medications such as combined oral contraceptives	↔ glecaprevir ↔ pibrentasvir	Coadministration of MAVYRET may increase the risk of ALT elevations and is not recommended.
Herbal Products:		
St. John's wort (*hypericum perforatum*)	↓ glecaprevir ↓ pibrentasvir	Coadministration may lead to reduced therapeutic effect of MAVYRET and is not recommended.
HIV-Antiviral Agents:		
Atazanavir	↑ glecaprevir ↑ pibrentasvir	Coadministration is contraindicated due to increased risk of ALT elevations *[see Contraindications]*.
Darunavir Lopinavir Ritonavir	↑ glecaprevir ↑ pibrentasvir	Coadministration is not recommended.
Efavirenz	↓ glecaprevir ↓ pibrentasvir	Coadministration may lead to reduced therapeutic effect of MAVYRET and is not recommended.
HMG-CoA Reductase Inhibitors:		
Atorvastatin Lovastatin Simvastatin	↑ atorvastatin ↑ lovastatin ↑ simvastatin	Coadministration may increase the concentration of atorvastatin, lovastatin, and simvastatin. Increased statin concentrations may increase the risk of myopathy, including rhabdomyolysis. Coadministration with these statins is not recommended.
Pravastatin	↑ pravastatin	Coadministration may increase the concentration of pravastatin. Increased statin concentrations may increase the risk of myopathy, including rhabdomyolysis. Reduce pravastatin dose by 50% when coadministered with MAVYRET.
Rosuvastatin	↑ rosuvastatin	Coadministration may significantly increase the concentration of rosuvastatin. Increased statin concentrations may increase the risk of myopathy, including rhabdomyolysis. Rosuvastatin may be administered with MAVYRET at a dose that does not exceed 10 mg.
Fluvastatin Pitavastatin	↑ fluvastatin ↑ pitavastatin	Coadministration may increase the concentrations of fluvastatin and pitavastatin. Increased statin concentrations may increase the risk of myopathy, including rhabdomyolysis. Use the lowest approved dose of fluvastatin or pitavastatin. If higher doses are needed, use the lowest necessary statin dose based on a risk/benefit assessment.
Immunosuppressants:		
Cyclosporine	↑ glecaprevir ↑ pibrentasvir	MAVYRET is not recommended for use in patients requiring stable cyclosporine doses > 100 mg per day.

↑= increase; ↓= decrease; ↔ = no effect

Drugs with No Observed Clinically Significant Interactions with MAVYRET

No dose adjustment is required when MAVYRET is coadministered with the following medications: abacavir, amlodipine, buprenorphine, caffeine, dextromethorphan, dolutegravir, elvitegravir/cobicistat, emtricitabine, felodipine, lamivudine, lamotrigine, losartan, methadone, midazolam, naloxone, norethindrone or other progestin-only contraceptives, omeprazole, raltegravir, rilpivirine, sofosbuvir, tacrolimus, tenofovir alafenamide, tenofovir disoproxil fumarate, tolbutamide, and valsartan.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

No adequate human data are available to establish whether or not MAVYRET poses a risk to pregnancy outcomes. In animal reproduction studies, no adverse developmental effects were observed when the components of MAVYRET were administered separately during organogenesis at exposures up to 53 times (rats; glecaprevir) or 51 and 1.5 times (mice and rabbits, respectively; pibrentasvir) the human exposures at the recommended dose of MAVYRET *[see Data]*. No definitive conclusions regarding potential developmental effects of glecaprevir could be made in rabbits, since the highest achieved glecaprevir exposure in this species was only 7% (0.07 times) of the human exposure at the recommended dose. There were no effects with either compound in rodent pre/post-natal developmental studies in which maternal systemic exposures (AUC) to glecaprevir and pibrentasvir were approximately 47 and 74 times, respectively, the exposure in humans at the recommended dose *[see Data]*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Glecaprevir

Glecaprevir was administered orally to pregnant rats (up to 120 mg/kg/day) and rabbits (up to 60 mg/kg/day) during the period of organogenesis (gestation days (GD) 6 to 18, and GD 7 to 19, respectively).

No adverse embryo-fetal effects were observed in rats at dose levels up to 120 mg/kg/day (53 times the exposures in humans at the recommended human dose (RHD)). In rabbits, the highest glecaprevir exposure achieved was 7% (0.07 times) of the exposure in humans at RHD. As such, data in rabbits during organogenesis are not available for glecaprevir systemic exposures at or above the exposures in humans at the RHD.

In the pre/post-natal developmental study in rats, glecaprevir was administered orally (up to 120 mg/kg/day) from GD 6 to lactation day 20. No effects were observed at maternal exposures 47 times the exposures in humans at the RHD.

Pibrentasvir

Pibrentasvir was administered orally to pregnant mice and rabbits (up to 100 mg/kg/day) during the period of organogenesis (GD 6 to 15, and GD 7 to 19, respectively). No adverse embryo-fetal effects were observed at any studied dose level in either species. The systemic exposures at the highest doses were 51 times (mice) and 1.5 times (rabbits) the exposures in humans at the RHD.

In the pre/post-natal developmental study in mice, pibrentasvir was administered orally (up to 100 mg/kg/day) from GD 6 to lactation day 20. No effects were observed at maternal exposures approximately 74 times the exposures in humans at the RHD.

Lactation

Risk Summary

It is not known whether the components of MAVYRET are excreted in human breast milk, affect human milk production, or have effects on the breastfed infant. When administered to lactating rodents, the components of MAVYRET were present in milk, without effect on growth and development observed in the nursing pups *[see Data]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MAVYRET and any potential adverse effects on the breastfed child from MAVYRET or from the underlying maternal condition.

Data

No significant effects of glecaprevir or pibrentasvir on growth and post-natal development were observed in nursing pups at the highest doses tested (120 mg/kg/day for glecaprevir and 100 mg/kg/day for pibrentasvir). Maternal systemic exposure (AUC) to glecaprevir and pibrentasvir was approximately 47 or 74 times the exposure in humans at the RHD. Systemic exposure in nursing pups on post-natal day 14 was approximately 0.6 to 2.2 % of the maternal exposure for glecaprevir and approximately one quarter to one third of the maternal exposure for pibrentasvir.

Glecaprevir or pibrentasvir was administered (single dose; 5 mg/kg oral) to lactating rats, 8 to 12 days post parturition. Glecaprevir in milk was 13 times lower than in plasma and pibrentasvir in milk was 1.5 times higher than in plasma. Parent drug (glecaprevir or pibrentasvir) represented the majority (>96%) of the total drug-related material in milk.

Pediatric Use

Safety and effectiveness of MAVYRET in children less than 18 years of age have not been established.

Geriatric Use

In clinical trials of MAVYRET, 328 subjects were age 65 years and over (14% of the total number of subjects in the Phase 2 and 3 clinical trials) and 47 subjects were age 75 and over (2%). No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects. No dosage adjustment of MAVYRET is warranted in geriatric patients.

Renal Impairment

No dosage adjustment of MAVYRET is required in patients with mild, moderate or severe renal impairment, including those on dialysis.

Hepatic Impairment

No dosage adjustment of MAVYRET is required in patients with mild hepatic impairment (Child-Pugh A). MAVYRET is not recommended in patients with moderate hepatic impairment (Child-Pugh B). Safety and efficacy have not been established in HCV-infected patients with moderate hepatic impairment. MAVYRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C) due to higher exposures of glecaprevir and pibrentasvir *[see Contraindications]*.

OVERDOSAGE

In case of overdose, the patient should be monitored for any signs and symptoms of toxicities. Appropriate symptomatic treatment should be instituted immediately. Glecaprevir and pibrentasvir are not significantly removed by hemodialysis.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Risk of Hepatitis B Virus Reactivation in Patients Coinfected with HCV and HBV

Inform patients that HBV reactivation can occur in patients coinfected with HBV during or after treatment of HCV infection. Advise patients to tell their healthcare provider if they have a history of hepatitis B virus infection *[see Warnings and Precautions]*.

Drug Interactions

Inform patients that MAVYRET may interact with some drugs; therefore, patients should be advised to report to their healthcare provider the use of any prescription, non-prescription medication or herbal products *[see Contraindications, Warnings and Precautions and Drug Interactions]*.

Administration

Advise patients to take MAVYRET recommended dosage (three tablets) once daily with food as directed. Inform patients that it is important not to miss or skip doses and to take MAVYRET for the duration that is recommended by the physician.

If a dose is missed and it is:

- Less than 18 hours from the usual time that MAVYRET should have been taken – advise the patient to take the dose as soon as possible and then to take the next dose at the usual time.
- More than 18 hours from the usual time that MAVYRET should have been taken – advise the patient not to take the missed dose and to take the next dose at the usual time.

Manufactured by AbbVie Inc., North Chicago, IL 60064

Ref: 03-B512 Revised August 2017

46A-1924296 **MASTER**

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Academy of Managed Care Pharmacy
Nexus 2017, Dallas, Texas
October 16-19, 2017

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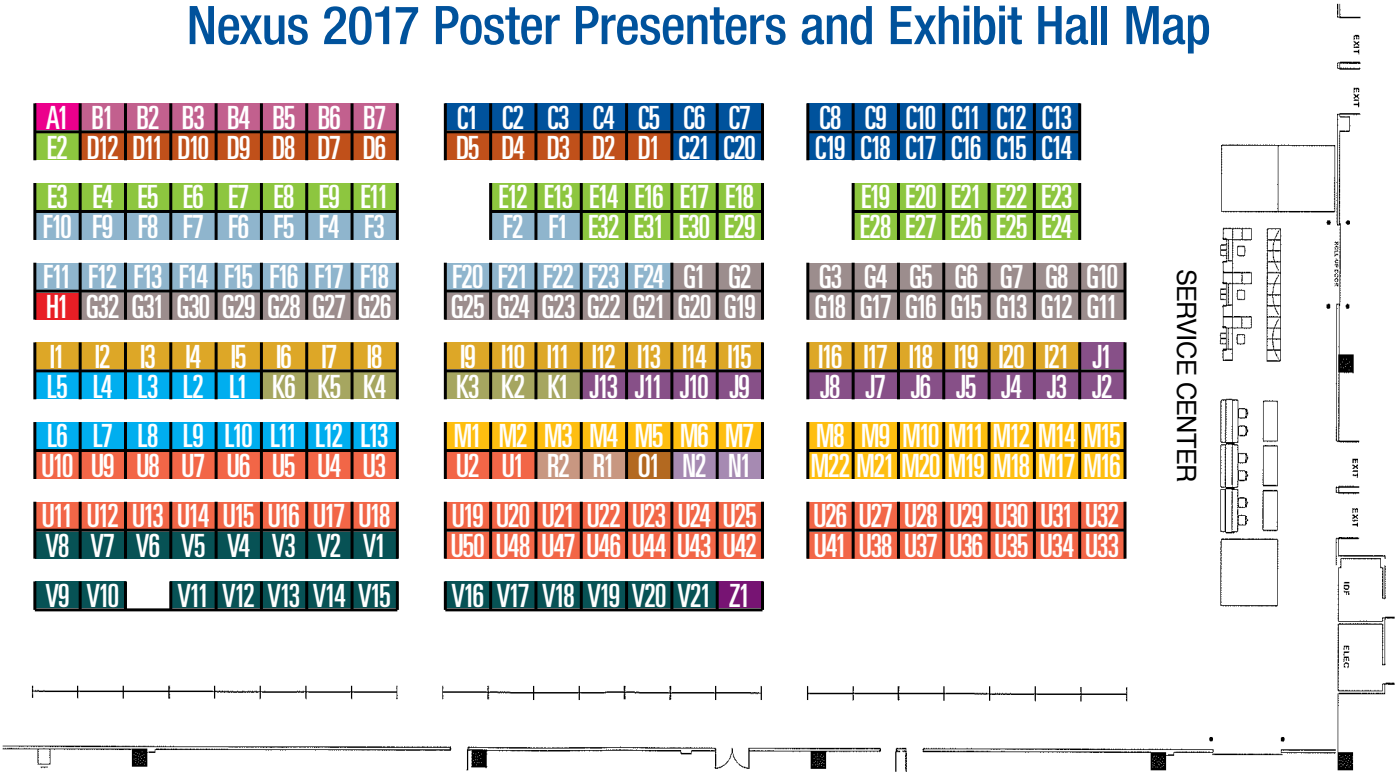

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V8 Adherence to Medications Following Medication Therapy Management Services
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V12 Medication Therapy Management Services and the Impact on Healthcare Utilization
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V14 Needs Assessment Survey for Translation of Pharmacogenetics into Clinical Practice at University of California San Francisco Health
V15 Differing Costs Between Episodes of Care Triggered by Abiraterone and Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer in Medicare Supplemental Plans
V16 The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey
V17 Systematic Review of Predictive Models for Opioid Abuse
V18 Status of Current Outcomes-Based Contracting Approaches and Future Thoughts
V19 The Effect of Combination Antiretroviral Treatment Regimens on Patient Medication Adherence and Overall Healthcare Utilization in the Human Immunodeficiency Virus Population
V20 Impact of Quality-Based Reimbursement on Physician Practice in Multiple Sclerosis Patient Care
V21 Is a Diabetes Value-Based Insurance Design Associated with Lower Costs?
Z1 Recommendations for Establishing Clinical Pharmacogenetic Counseling Centers: A Comprehensive Literature Review

Medal Winning Abstracts

Each abstract was assessed by reviewers using a 1-5 scale on the following 5 criteria: relevance, originality, quality, bias, and clarity. These are the same criteria used by *JMCP* to evaluate manuscripts. The abstract's mean score on the 5 criteria was used to award Platinum, Gold, Silver, or Bronze medals.

Eric P. Borrelli, PharmD Candidate, MBA Candidate, [L11] Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis with Antiepileptic Drugs: An Analysis of the FDA Adverse Event Reporting System

Erin A. Ferries, PhD, [V12] Medication Therapy Management Services and the Impact on Healthcare Utilization

Pengxiang Li, PhD, [G14] Impact of Cost Sharing on Adherence to Disease-Modifying Therapy Among Medicare Part D Patients with Multiple Sclerosis

Shelley Zhang, BS, PharmD Candidate, [F7] Impact of a Retrospective Drug Utilization Review Program on Concomitant Opioid and Benzodiazepine Use

Nancy M. Albert, PhD, [I12] Reduction in Hospitalization and Medical Costs Among Patients Initiated with Sacubitril/Valsartan: Insights from an Administrative Database in the United States

Srinivas Annavarapu, MBBS, PhD, [J7] Spirometry Evaluation to Assess Performance of a Claims-Based Predictive Model to Identify Patients Likely to Have Undiagnosed Chronic Obstructive Pulmonary Disease

John A. Carter, MS, [F6] Determining the Economic Impact of Medication Nonadherence in Persons Treated with Depot-Injectable or Sublingual Buprenorphine for Opioid Use Disorder

Tam Dang-Tan, PhD, [E14] Real-World Effectiveness of Liraglutide Versus Sitagliptin Among Patients Enrolled in a Medicare Advantage Prescription Drug Plan

Manasi Datar, PhD, [I11] Comparison of Stroke, Venous Thromboembolic Events, and Other Outcomes for Patients with Nonvalvular Atrial Fibrillation Treated with Novel Oral Anticoagulant Agents or Warfarin

Babafunlola Davis, PharmD, BCPS, BCACP, [J6] Pharmacist-Initiated Albuterol Order Optimization and Education in an Adult Asthma Population

Zenobia Dotiwala, MS, [J10] Association of Elevated Peripheral Blood Eosinophil Counts and Resource Use in Patients with Asthma

Nilesh Gangan, MS, [J12] Relationship Between Performance on the Medication Management for Asthma Quality Measure and Asthma-Related Physician Office Visits and Emergency Department Visits: Implications for Quality Improvement Strategies

Santosh Gautam, [E12] Factors Associated with Glycemic Control Among Patients with Type 2 Diabetes Enrolled in Medicaid

Patrick P. Gleason, PharmD, [V21] Is a Diabetes Value-Based Insurance Design Associated with Lower Costs?

Chad C. Henry, PharmD, [U20] Implementing Pharmacogenomic Consultation into Prescribing

Anne Kangethe, PharmD, MPH, PhD, [F5] Real-World Health Care Cost of Substance Abuse for Patients Receiving Face-to-Face Therapy Versus Without Therapy

Edward M. Kerwin, MD, [J5] The Adoption of Short-Acting Beta-Agonist Inhalers with Integrated Dose Counters in a Managed Care Plan: A Budget Impact Model

Carol Mansfield, PhD, [G26] Patient Preferences for Preventive Migraine Treatments: A Discrete-Choice Experiment

Daniel McBryan, MD, [J8] Assessment in a Real-World Setting of the Effect of Inhaled Steroid-Based Triple Therapy Versus the Combination of Tiotropium and Olodaterol on Reducing Chronic Obstructive Pulmonary Disease Exacerbations: AIRWISE Study Design

Tessa Rife, PharmD, BCGP, CACP, [E26] An Electronic Intervention to Improve Safety of Testosterone Replacement Therapy at San Francisco Veterans Affairs Health Care System

Jonathan Schelfhout, PhD, [D8] Resource Utilization Associated with Cytomegalovirus in Hematopoietic Stem Cell Transplant Recipients: A Commercial Payer Perspective

Dana Stafkey-Mailey, PharmD, PhD, [E16] Validation of an Algorithm to Identify Death in Administrative Claims Data

S. Scott Sutton, PharmD, BCPS-AQ ID, [B7] Fracture Rates in U.S. Veterans with and without HIV: A Cohort Study, 2000-2016

Jeffrey Trocio, MPH, [I10] Risk of Major Bleeding and Stroke in Nonvalvular Atrial Fibrillation Patients Adherent to Oral Anticoagulants

Anna Wallace, PhD, MPH, [J9] Health-Care Resource Utilization, Costs, and Exacerbation Rates in Patients with COPD Stratified by GOLD Airflow Limitation Classification in a U.S. Commercially Insured Population

Jerry S. Wong, PharmD, MBA, [E13] Clinical and Financial Outcomes of Switching Insulin Glargine to Insulin Detemir in an Ambulatory Care Services Countywide Health System.

Zobair M. Younossi, MD, [K6] Inpatient Mortality, Payer Status, and Length of Inpatient Stay for U.S. Liver Transplant Recipients with Primary Biliary Cholangitis: Data from the Scientific Registry of Transplant Recipients

Jingbo Yu, PhD, [D10] Healthcare Resource Utilization and Costs of Care Among Patients with Acute Graft-Versus-Host Disease Post-Allogeneic Hematopoietic Stem Cell Transplant in a Large Managed Care Plan

Stephanie Yu, PharmD, [E11] Metabolic Outcomes for Type 2 Diabetes Patients on New Antidiabetes Classes Compared with Those on Traditional Classes in Central Texas

Medal Winning Abstracts *(continued)*

Myrlene S. Aigbogun, MPH, [G7] Healthcare Resource Utilization and Costs of Behavioral Disturbances in Dementia

Carrie M. Armstrong, PharmD, MBA, [E8] Impact of Long-Acting and Non-Long-Acting Insulin Utilization on A1c Among Type II Diabetics in a Medicaid Population

Christina Bulkley, PharmD, [F22] Academic Detailing for Attention-Deficit/Hyperactivity Disorder in Oklahoma Medicaid

Tyler B. Earley, PharmD Candidate, [V10] Analysis of Prescription Claims Data for Potentially Inappropriate Anticholinergic Drug Use Among the Geriatric Population

Elly Fatehi, PharmD, MPH, BCPS, [U19] Evaluation of an Opioid Management Program in a Medicaid Managed Care Organization

Christopher Graham, MS, [D9] Cost Savings Associated with Subcutaneous C1-Inhibitor (Human) Long-Term Prophylaxis for Hereditary Angioedema

Marc Hixson, MBA, [K5] Plecanatide for Treating Chronic Idiopathic Constipation: A Pooled Analysis of Efficacy and Safety

Qinli Ma, PhD, [C20] Risk of Neutropenic Hospitalization in Non-Hodgkin's Lymphoma Cancer Patients Receiving Chemotherapy

Siva Narayanan, MHS, MS,PhD, [M16] Dosing Patterns Associated with Deflazacort Observed in the Early Access Program for Patients with DMD in the United States

Kurt R. Oelke, MD, [L8] Persistence and Adherence with Subcutaneously Administered Biologics Among Biologic-Naive and Biologic-Experienced Patients with Psoriatic Arthritis: Analyses from a U.S. Claims Database

Corrie Sanders, PharmD Candidate, [V11] Polypharmacy Rates of Central Nervous System-Active Agents in the Geriatric Population

Jason Shafrin, PhD, [F10] Prescriber's Response to Noncompliance Information: A Claims-Based Analysis of Patients with Serious Mental Illness

Stacie A. Smith, PharmD, MBA, [V16] The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey

Catherine I. Starner, PharmD, [F4] Opioid Utilization and Cost: A 3-Year Look Among 15 Million Commercially Insured Members

Bingcao Wu, MS, [V15] Differing Costs Between Episodes of Care Triggered by Abiraterone and Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer in Medicare Supplemental Plans

Fang Liz Zhou, MD, [E9] Lower Hypoglycemia Risk and Better Persistence in Adults with Type 2 Diabetes After Switch to Insulin Glargine 300 U/mL Versus Other Basal Insulins in Real-World Clinical Settings

Jay Bae, PhD, [E6] Basal Insulin Use Behaviors, Attitudes, and Adherence Among Type 2 Diabetes Patients: An Analysis of Patient Survey Data

Kaustuv Bhattacharya, MS, [F23] Impact of a Coordinated Care Program on Costs and Outcomes of Children with Mental Illnesses in Mississippi Medicaid

Steven R. Feldman, MD, PhD, [L7] Comparison of Real-World Healthcare Costs Among Biologic-Naive Psoriasis Patients Initiating Apremilast or Biologics

Anne Kangethe, PharmD, MPH, PhD, [B6] Real-World Health Plan Data Analysis: Key Trends in Medication Adherence and Overall Costs in Patients with HIV

Ece Mutlu, MD, [K4] Real-World Utilization of Biosimilar and Originator Infliximab in a Cohort of Patients with Inflammatory Bowel Disease in Turkey

Gary M. Oderda, PharmD, MPH, [R1] Burden of Postoperative Nausea and Vomiting Associated with Acute Postoperative Pain Treatment

Joseph Tkacz, MS, [M8] Healthcare Resource Use and Costs Associated with Biologic Switching in Rheumatoid Arthritis

Weijia Wang, MSc, [E7] The Direct Cost of Cardiovascular Disease-Related Death in Patients with Type 2 Diabetes Mellitus in a Medicare Population

Jonathan H. Watanabe, PharmD, PhD, BCGP, [F18] Anxiety and Depression Symptoms and Every Night Sleep Medication Use in Older Adults in the United States

Jashin J. Wu, MD, [L6] Minimal Clinically Important Difference for Work Productivity and Activity Impairment Questionnaire in Psoriasis Patients

Podium Abstracts
(Presentations: Wednesday, October 18, 8:00 am-9:30 am)

F7 Impact of a Retrospective Drug Utilization Review Program on Concomitant Opioid and Benzodiazepine Use

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BACKGROUND: Concomitant use of opioids and benzodiazepines (BZD) can potentiate fatal opioid overdose, and is advised against through boxed warnings by the U.S. Food and Drug Administration. A previous drug utilization review (DUR) program reduced opioid and central nervous system drug combination therapy by 28.1%. The impact of implementing a similar DUR program to reduce co-prescribing of opioids and BZDs is unknown.

OBJECTIVE: To determine the effectiveness of a retrospective DUR program in reducing the number of patients on chronic combination therapy of high-dose opioids and BZDs.

METHODS: Pharmacy claims data from a commercial health plan in the Midwest was queried to identify members prescribed with concomitant opioids and BZDs. Members who met criteria were continuously enrolled, had claims for a daily dosage of opioids >200 morphine milligram equivalents (MME) for 90 consecutive days, and had a 120-day supply of a BZD during the 365-day review period (11/4/15-11/4/16). Concomitant use was defined by an overlap of day supply on the last day of the review period. For each member identified, a medication profile and survey on the usefulness of the information were faxed to the most recent prescriber(s) of a high-dose opioid or BZD. Prescribers were asked to re-evaluate the members' medication therapy. The DUR criteria was reassessed six months post-intervention and pre-post results were compared using paired samples t-tests.

RESULTS: A total of 174 members met criteria for the DUR intervention. Post-intervention, 73 members remained eligible, indicating a 51.0% reduction in concurrent opioid and BZD therapy. While change in total daily MME was non-significant (387.6 vs. 387.5, $P=0.995$), the DUR program significantly decreased the number of unique opioids per member (2.3 vs. 1.9, $P<0.001$). Survey response rate was 23.0% (n=49). The 213 prescribers that received DUR intervention were distributed in family medicine (20.2%), internal medicine (16.0%), psychiatry (7.0%), pain management (6.6%), other (17.8%), and unknown (32.4%). After receiving the fax, 41.4% reported no changes to pain management therapy, 17.2% decreased the opioid dose, 3.4% discontinued the opioid, and 8.6% reported other changes. A majority of prescribers (63.1%) found the information useful.

CONCLUSIONS: The 51.0% reduction in concurrent opioid and BZD therapy suggests that more focused DUR programs result in greater improvements in prescribing habits. Similar programs can identify members at risk for fatal respiratory depression or overdose.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

G14 Impact of Cost Sharing on Adherence to Disease-Modifying Therapy Among Medicare Part D Patients with Multiple Sclerosis

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BACKGROUND: Disease-modifying therapies (DMTs) reduce relapse rates and disability progression for relapsing multiple sclerosis (MS). However, MS DMTs are often subject to high out-of-pocket (OOP) costs, especially under Part D which typically requires 25%-33% coinsurance (initial coverage phase), followed by 45%-50% coinsurance (coverage gap phase), and then 5% coinsurance (catastrophic phase) during the calendar year with the cycle resetting every January 1.

OBJECTIVE: To examine the impact of Part D cost sharing on monthly DMT adherence among patients with MS.

METHODS: This retrospective claims analysis used 2011-2014 Medicare files to examine DMT use in MS patients without low-income subsidies ("non-LIS group") as they transition through various Part D cost-sharing levels, as compared to a contemporaneous group of full LIS patients ("LIS group"), who faced nominal or no cost-sharing. The sample included fee-for-service Part D patients who were adherent (proportion of days covered [PDC] >0.80) to their Part D DMTs during the catastrophic phase in each month of the last quarter of the prior year. Outcomes included monthly adherence to Part D DMTs (PDC >0.80) in the study calendar year. GEE logistic regressions controlling for sociodemographic, clinical, and plan formulary characteristics were used to estimate risk adjusted adherence rates.

RESULTS: The sample included 4,783 non-LIS and 11,188 LIS patients, all of whom were adherent in October to December of the previous year with mean monthly OOP costs of ~$250 and $0, respectively. In January of the following year, the mean monthly OOP costs increased to $1,621 and $4 for non-LIS and LIS patients, respectively. Correspondingly, risk-adjusted adherence rates dropped in both groups but non-LIS patients were significantly less likely to be adherent to DMTs than LIS patients during January (65% vs. 80%; $P<0.001$). The mean number of days to enter the catastrophic phase which resulted in lower OOP costs was ~50 days across both groups. Correspondingly, monthly adherence rates increased in non-LIS patients and became equal (82%) for both groups by March, remaining similar until the end of the year. Similar results were found in subgroups by disability and relapse history; however, risk-adjusted adherence rates in January were significantly poorer in non-LIS patients who were Black (53%) vs. White or other races (66%).

CONCLUSIONS: Increased Part D cost sharing was associated with lower DMT adherence, especially among Blacks. Future research should evaluate its impact on clinical outcomes.

SPONSORSHIP: Biogen.

L11 Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis with Antiepileptic Drugs: An Analysis of the FDA Adverse Event Reporting System

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BACKGROUND: Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) are rare and life threatening adverse skin reactions often triggered by particular medications. Although once thought to be separate conditions, they are now considered part of a continuum, with SJS defined as a detachment of less than 10% of body surface area (BSA) and TEN defined as greater than 30% of BSA. One class of medications that has the highest frequency of SJS and TEN reactions are antiepileptic drugs (AEDs).

OBJECTIVE: To determine and compare the reports of SJS/TEN adverse reactions within the AED class of medications.

METHODS: We reviewed adverse event reports from the FDA Adverse Event Reporting System (FAERS) for a 30-month time frame of July 2014 through December 2016. Follow-up reports were excluded along with reports missing all three of the following categories: event date, sex, and age. A broad search term for SJS and TEN was used and subsequent listings of adverse events were reviewed for inclusion. The proportional reporting ratio (PRR), reporting odds ratio (ROR), and corresponding 95% confidence intervals (CI) were calculated compared to other AEDs using OpenEpi. AEDs were classified as any medication with FDA indication for epilepsy or seizures.

RESULTS: There were 1,995,573 total adverse reactions of any type reported during this time frame, with SJS (474 ADRs) and TEN (259 ADRs) comprising a total of 733 adverse reactions. Reports of SJS/TEN reactions were more frequently attributed to AEDs (138, 18.8%) than any other drug class. The AEDs as a class had a ROR of 8.634 (CI: 6.949-10.07) and a PRR of 8.345 (CI: 6.936-10.04) compared to all other medications. The AEDs with the highest ROR and PRR were zonisamide with a ROR of 11.41 (CI: 5.279-24.64) and PRR of 11.12 (CI: 5.252-23.56), lamotrigine with a ROR of 9.958 (CI: 7.124-13.92) and PRR of 9.834 (CI: 7.053-13.71), clorazepate with a ROR of 9.13 (CI: 1.248-66.76) and PRR of 8.945 (CI: 1.279-62.53), rufinamide with a ROR of 8.352 (CI: 1.144-60.96) and PRR of 8.199 (CI: 1.171-57.43), and phenytoin with a ROR of 3.713 (CI: 2.049-6.729) and PRR of 3.689 (CI: 2.046-6.653). Overall, AEDs were associated with a 2.5-fold increase in reports for SJS/TEN compared with NSAIDs which was the second most reported class.

CONCLUSIONS: Steven-Johnsons Syndrome and toxic epidermal necrolysis are rare but life-threatening reactions. The AED class has a 2.5 times higher prevalence of SJS/TEN when compared to the second leading drug class. Caution should be used when prescribing AEDs, especially in patients with a higher risk of developing these conditions.

SPONSORSHIP: None.

V12 Medication Therapy Management Services and the Impact on Healthcare Utilization

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BACKGROUND: Medication therapy management (MTM) services are conducted by Medicare Prescription Drug Plan sponsors via comprehensive medication review (CMR) or targeted medication review (TMR) as required by the Centers for Medicare and Medicaid Services. MTM services are intended to optimize medication use and should lead to improved outcomes, but real-world evidence of MTM effectiveness is limited.

OBJECTIVE: The objective of this study was to compare patients participating in MTM services (CMR and/or TMR) to eligible, non-participating patients on acute inpatient (IP) admissions and emergency department (ED) visits.

METHODS: The retrospective, cohort analysis of patients eligible for MTM in 2014 utilized Humana's administrative claims data. MTM participants were 1:1 propensity score matched to eligible, non-participants who refused services or could not be reached, and were matched on MTM service type received or that they were eligible to receive: CMR only, TMR only, or CMR+TMR. Trend-adjusted outcomes for IP admissions and ED visits were analyzed among the cohorts for 12 months post MTM service/eligibility. Changes from pre-index through post-index for non-participants were used to establish the expected trend. Post-index IP admissions and ED visits for participants were then compared to pre-index participant IP admissions and ED visits multiplied by the expected IP admission and ED visit trends, respectively.

RESULTS: The study identified 64,801 CMR-only, 5,692 TMR-only, and 9,876 CMR+TMR participants matched to eligible non-participants. For patients receiving CMR-only, differences in IP admissions and ED visits for participants versus non-participants were not evident. TMR-only participants had 55.2 fewer trend-adjusted IP admissions per 1,000 patients than nonparticipants (95% CI: 29-81 fewer per 1,000); differences in ED visits were not evident. CMR+TMR participants had 62.1 fewer trend-adjusted IP admissions per 1,000 patients than nonparticipants (95% CI: 43-82 fewer per 1,000); differences in ED visits were not evident.

CONCLUSIONS: Patients receiving TMR services, or CMR+TMR, are most likely to benefit from MTM services given the reduction found in IP admissions. CMR services alone did not provide benefit to participants, relative to non-participants. Given the increasing importance of optimal medication utilization, it is essential to understand which MTM services will produce positive clinical outcomes among eligible patients.

SPONSORSHIP: Humana.

Nexus-Themed Reviewed Abstracts: Value-Based Health Care

(Presentations: Wednesday, October 18, 12:00 pm-2:45 pm)

V01-V21 Value-Based Health Care: Identifying Benefits for Patients, Providers, and Payers

V1 Leveraging Real-World Evidence to Better Inform Comparative Effectiveness Research and Support Value-Based Health Care

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Amaris

BACKGROUND: While not mandatory, the AMCP Format strongly recommends that evidence from comparative effectiveness research (CER) is included in the manufacturer submission. Bayesian network meta-analysis (NMA) has become standard practice in CER. NMAs typically only include randomized clinical trials (RCT) based on the hierarchy of evidence. Real world evidence (RWE)-i.e., non-randomized studies, electronic health records, disease registries, claims data-is increasingly used in value-based health care.

OBJECTIVE: To review and critically appraise methods combining different levels of evidence, contrast these methods with Health Technology Assessment (HTA) and regulatory agencies recommendations to provide health care decision makers with a critical review of methodological approaches.

METHODS: A systematic literature review was designed to identify methodological papers and NMAs combining various study designs. Searches were conducted in PubMed and Embase. Hand searches consisted of reviewing citations found in included publications and searching conference proceedings, HTA and regulatory agencies' websites, and methodological guidelines.

RESULTS: Four main methods for combining evidence from different study designs were identified: naive pooling of all types of evidence, conducting a design-adjusted analysis, using non-randomized evidence as prior information, and running a three level hierarchical model. While these methods should be performed after a risk of bias assessment, they present advantages (i.e. precision and network connection is optimized by including more evidence, bias associated with non-randomized data is modelled, NMA outputs generated are more generalizable). These methods were also associated with drawbacks (i.e. introduction of bias by including non-randomized trials, subjective selection of adjustment parameter values). Current HTA guidelines do not discuss these methods in detail. Guidance on the use of RWE by the FDA for medical device regulatory submissions and by NICE for the estimation of treatment effects in decision making was identified.

CONCLUSIONS: Given the lack of published guidance in this research area, the methods reviewed are considered exploratory and their perception by HTA agencies is unclear. Further research should be conducted to address the bias inherent to pooling data from different sources. Combining RWE and RCTs would help lead to a more generalizable comparative effectiveness assessment of health technologies in the context of AMCP Format submission.

SPONSORSHIP: None.

V2 Economic Implications of Hyperkalemia in a U.S. Managed Medicaid Population

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BACKGROUND: Hyperkalemia (HK) is a serious medical condition that can result in life-threatening arrhythmias and sudden cardiac death, particularly in patients with cardiorenal conditions, but its economic impact is not well characterized in the managed Medicaid (MM) population.

OBJECTIVE: This study evaluated the economic impact of HK on cardiorenal patients in the MM population.

METHODS: This retrospective cohort study used a MM claims database of 3,563 patients (973 HK patients, 2,590 controls matched on age, comorbidities and eligibility status/time period) over a 30-month period from 2013 to 2016. The inclusion criteria for the HK cohort were ≥18 years of age, Medicaid only payer status, listed cardiorenal diagnosis (chronic kidney disease/end-stage renal disease, congestive heart failure, hypertension, diabetes) and a HK claim during the study period.

RESULTS: After matching, HK patients had 2-fold higher mean healthcare costs (medical and drug) as compared with the control cohort ($56,002 vs. $23,653 per member per year [PMPY]). These cost differences were driven by medical costs ($49,648 and $18,399 PMPY for the HK and control cohorts, respectively). Two of the largest drivers of medical cost variance were inpatient costs ($33,116 vs. $10,629 PMPY for the HK and control cohorts respectively) and dialysis costs ($2,716 vs. $810 PMPY for HK and control cohorts, respectively). The medical loss ratio (MLR) was 552% for the HK cohort and 260% for the control cohort. Both cohorts yielded revenue deficits but the HK cohort had a 2-fold greater loss.

CONCLUSIONS: This real-world cohort study suggests that among Medicaid patients with cardiorenal conditions, HK increases healthcare utilization and costs, primarily driven by inpatient and dialysis costs. Based on the extremely high MLR of HK cohort, enhanced HK monitoring and management should be considered.

SPONSORSHIP: Relypsa.

V3 Denial Rates and Prescriber Satisfaction with a State-Mandated Standard Prior Authorization Form: A Health Plan's Experience

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BACKGROUND: Prior authorization (PA) programs are utilized to ensure the safest, most effective use of medications while decreasing unnecessary use and cost. Many payers inform prescribers of PA coverage requirements on their PA forms that include drug specific criteria. However, Michigan Public Act 218 of 1956 requires all payers to use the same standard PA form in efforts to simplify information exchange between prescribers and payers. Michigan implemented a standard PA form on July 1, 2016; currently 10 states utilize a standard PA form.

OBJECTIVE: To evaluate denial rates and prescriber satisfaction pre and post implementation of a standard PA form.

METHODS: PA denial rates of Blue Cross Blue Shield of Michigan commercial members were analyzed for a 10 month period pre (9/1/15-6/30/16) and post (7/1/16-4/30/17) implementation of a standard PA form. The following inclusion criteria must be met throughout the study period: drugs with ≥10% increase in denial rate; case volume ≥50; consistent PA requirements. Drugs were excluded from analysis if PA criteria changed during the study period. The analysis focused on high volume drugs with increased denial rates to identify opportunities for improvement with the PA process. Top 500 prescribers by PA volume were faxed a survey during spring 2016 and fall 2016 to assess prescriber satisfaction pre and post implementation, respectively.

RESULTS: A total of 24 drugs' denial rates increased ≥ 10% with at least 50 cases submitted during the study period. Most impacted categories within the top 24 drugs included acne (n=4, 16.7%), weight loss (n=4, 16.7%), migraine (n=3, 12.5%), gastrointestinal (n=2, 8.3%), and testosterone (n=2, 8.3%). Survey response rate was >20% (pre: 23.4%; post: 22.2%). Majority of prescribers report preferring a medication specific PA form with specific criteria (pre: 81.2%, post: 76.6%), and that specific PA form is their main source for knowing payer specific criteria (pre: 83.8%, post: 74.7%). Prior to implementation, most prescribers (76.1%) felt that a standard form would not provide a quicker turn-around-time (TAT), and 72% report not experiencing a quicker TAT post implementation of the standard form.

CONCLUSIONS: Increased denials were experienced 10 months post implementation of a state mandated standard PA form. Prescriber education of payer PA requirements may help streamline the PA process.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

V7 Impact of a Pharmacist Intervention on CMS Star Ratings for Statin Use in Persons with Diabetes

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PROBLEM DESCRIPTION: Statin use in persons with diabetes (SUPD) moved from a CMS Display Measure to a Star Ratings Measure in 2017. To improve the quality of care delivered to Medicare beneficiaries, Kaiser Permanente Georgia (KPGA), a managed care organization, developed and implemented a pharmacist-led intervention designed to specifically address the gaps in care for SUPD.

GOAL: To measure the impact of a pharmacist-led intervention on the proportion of Medicare beneficiaries with diabetes utilizing statins.

PROGRAM DESCRIPTION: The SUPD measure is calculated by taking the proportion of member-years of enrolled Medicare beneficiaries 41 to 75 years of age who were dispensed two or more prescription fills for a hypoglycemic drug and received a prescription fill for a statin or statin combination during the same measurement year as compared to those who did not. The pharmacist-led intervention was implemented to improve the initiation and utilization of statins in diabetics. KPGA targeted beneficiaries deficient in a statin or statin combination and identified additional clinical parameters and criteria. Inclusion criteria: diabetes diagnosis; exclusion criteria were: LDL<70, dialysis, liver function tests >3 times upper limit of normal, history of rhabdomyolysis. Once a statin was deemed clinically appropriate, the pharmacist initiated the statin prescription under physician authorization, ordered labs as appropriate, and counseled individual beneficiaries on importance of statin therapy.

OBSERVATIONS: In September 2016, approximately 500 beneficiaries were identified for outreach on a one-time basis. Of the 500 beneficiaries, 88% were deemed clinically eligible for statin therapy. A statin prescription was initiated in 58% of those clinically eligible with an 84% fill rate after pharmacist-led intervention. This resulted in a 5% increase in the overall SUPD CMS display rating. The intervention resulted in above average performance when compared to the reported average of other Part D plans.

FINDINGS/RECOMMENDATIONS: Individualized review is required to determine if a statin is clinically appropriate. For managed care organizations working in a collaborative environment with access to an electronic health record system and pharmacy fills data, this intervention proved successful to improve CMS Star Ratings. Sustainability of this one-time intervention is being evaluated as part of KPGA's long-term strategy. Although the guidelines and literature support statin use, beneficiaries and prescribers continue to have misconceptions concerning potential side effects and therapy duration.

SPONSORSHIP: None.

V8 Adherence to Medications Following Medication Therapy Management Services

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BACKGROUND: Medication therapy management (MTM) programs have been introduced to address medication nonadherence. MTM services can be delivered via a comprehensive review of a patient's medications, or targeted to a specific medication-related problem, known as a Targeted Medication Review (TMR). TMRs generally follow an alert identifying an issue such as medication nonadherence.

OBJECTIVE: The objective of this study was to evaluate the impact of TMRs on medication adherence among patients with a nonadherence alert.

METHODS: A retrospective, cohort analysis of Humana's administrative claims data was used to analyze patients eligible for MTM programs in 2014 with a nonadherence alert for oral medication for diabetes, hypertension, or lipid disorder (statin). A diagnosis for the relevant condition was verified via medical claims. Patient's receiving a TMR (participants) were propensity score (PS) matched to non-participants who were eligible to receive a TMR for nonadherence, but refused services or could not be reached. The proportion of patients shifting from nonadherent in the 6 months pre-TMR to adherent (proportion of days covered ≥0.80) in the 6 months post TMR was examined.

RESULTS: A total of 3,474 TMR participants with a nonadherence alert were identified and matched 1:1 to TMR-eligible non-participants. A larger percentage of participants than non-participants shifted to become adherent in each cohort: 7% more for diabetes ($P=0.15$), 13% more for hypertension ($P<0.01$), and 11% more for statin users ($P<0.01$).

CONCLUSIONS: Identifying methods to improve adherence among this population is crucial. The results of this analysis demonstrate conducting TMRs for nonadherence improves patient adherence to chronic medications. Targeting these specific medication adherence problems through TMRs can result in more effective patient therapeutic management.

SPONSORSHIP: Humana.

V9 U.S. Payer Perspectives on Patient-Reported Outcomes in Oncology

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BACKGROUND: Patient-reported outcomes (PROs) are increasingly used in oncology clinical trials and recognized in health care decision making. Understanding U.S. payer perspectives on PROs in oncology is critical for successful value communication and market access of new oncology treatments.

OBJECTIVE: To understand current and anticipated near-term future use of oncology PRO data in U.S. payer decision making.

METHODS: In-depth phone interviews with 13 U.S. managed care representatives and 5 oncologists between November 14 and 28, 2016. Interviewees were provided with background information on FDA statements encouraging incorporation of the patient's perspective into clinical studies, and on the National Cancer Institute's PRO-CTCAE system for collecting PROs on cancer treatment toxicities.

RESULTS: Payers and their oncology advisors understand what constitutes a PRO and describe it as a way to "gather what is important to patients in an unfiltered manner." Consideration of PRO data in decision making is not standardized and is reviewed on a case-by-case basis, if reviewed at all. Most respondents (13/18) were open to or have considered PRO data; however, PRO data are considered less useful than efficacy and safety data for clinical, formulary, or drug management decisions because (1) PRO measures differ across clinical trials and are therefore difficult to use for comparative purposes; (2) survival, recurrence, and cost are perceived as more important for both payers and patients; and (3) PROs are difficult to translate into meaningful outcomes (e.g., adherence and persistence to therapy, cost offsets, resource utilization). Study participants anticipate that PRO data will continue to gain prominence, and highlighted measure standardization and a focus on tangible outcomes such as toxicity, impact on activities of daily living, and related cost impacts rather than abstract quality of life measures as important factors in gaining broader acceptance. However, payers are waiting for others to define standards or impose requirements related to PROs. Payers and their oncology advisors generally were unaware of FDA guidance on PROs or PRO-CTCAE, but consider PRO-CTCAE a useful step in standardizing collection of PROs related to toxicity.

CONCLUSIONS: U.S. payers and oncologists identified a number of obstacles to more consistent payer use of PROs. Standardization and tangible focus of PRO measures and clear guidance from regulators or other authorities are considered key factors that will influence the future role of PROs in payer decision-making.

SPONSORSHIP: Pfizer.

V10 Analysis of Prescription Claims Data for Potentially Inappropriate Anticholinergic Drug Use Among the Geriatric Population

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BACKGROUND: The American Geriatric Society 2015 Updated Beers Criteria recommends against the concurrent use of two or more anticholinergic agents due to increased risk for adverse effects. The AGS panel compiled several scales ranking medications with strong anticholinergic activity. An association has been shown between concurrent anticholinergic medication use and an increased risk of dementia, cognitive impairment, falls, and hospitalizations in the geriatric population. Analysis of this population can help formulate prevention strategies and improve the quality of care that is received.

OBJECTIVE: The aim of this retrospective analysis was to determine the frequency of combinations of anticholinergic medications used by the geriatric population. The most frequently utilized anticholinergic medication and combination therapies were identified. This study aims to highlight the prevalence of potentially inappropriate medications used in practice today.

METHODS: This was a retrospective study of Anthem prescription claims data from the 2016 calendar year. Members included in the study were aged 65 years and older with two or more fills for the same anticholinergic medication with unique fill dates. Furthermore, members who filled at least one other anticholinergic medication with strong anticholinergic properties, based on recommendations from the AGS, more than once during the study period were included in the final analysis. The members with 30 days or more of overlapping supply of medication failed the polypharmacy measure.

RESULTS: Of the 78,266 members who had claims for anticholinergic medications, 4,053 (5.2%) failed the polypharmacy measure. There were 3,161 (78%) women who failed the measure. The most common drugs used by members who failed the measure were oxybutynin (16.8%), paroxetine (14.8%), and amitriptyline (9.6%). The two drug combination used the most by members was oxybutynin and paroxetine (9.5%).

CONCLUSIONS: The use of oxybutynin may be associated with a diagnoses of incontinence and lack of safer alternatives. The high rates of paroxetine use is concerning due to its strong anticholinergic properties. Beers List alternatives like sertraline, citalopram, and bupropion may provide safer options in the geriatric population. Further studies could be done to analyze hospitalizations in the geriatric population that failed the measure. Additionally, cost saving analysis based on prevention of hospitalizations is another area of opportunity for further research.

SPONSORSHIP: Anthem.

V11 Polypharmacy Rates of Central Nervous System-Active Agents in the Geriatric Population

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BACKGROUND: The American Geriatric Society 2015 Updated Beers Criteria recommends against concurrent use of three or more Central Nervous System-Active (CNS-Active) agents due to an increased risk for adverse effects. These harmful combinations may cause falls resulting in fractures and an increased cost in overall healthcare expenditure due to ER visits, mobility issues and risk for recurrent falls. An April 2017 analysis published in *JAMA* showed that polypharmacy trends of such agents in outpatient elderly individuals are trending upward. Examination from a population perspective may establish trends to implement prevention strategies.

OBJECTIVE: The goal of this observational retrospective analysis was to determine the prevalence of polypharmacy of CNS-active agents. This study aims to highlight harmful medication combinations used in practice today.

METHODS: A retrospective study was conducted using prescription claims data from Anthem in the 2016 calendar year. The eligible population included individuals 65 years of age or older with two or more fills for the same CNS-active medication during a treatment period of

30 days or more. Members were marked as "treatment failures" if they were on 3 or more CNS-active agents.

RESULTS: Of the 252,573 members with CNS-active claims, 12,094 (4.78%) experienced treatment failures. 74.0% of failures were seen in females and the classes most commonly reported experiencing treatment failures were benzodiazepines and selective serotonin reuptake inhibitors (SSRIs). Hydrocodone (11.3%) accounted for the most use far surpassing the second and third medications of alprazolam (8.39%) and oxycodone (7.4%). It was found that the most commonly prescribed harmful combinations included the same three classes: benzodiazepines, opioids and SSRIs.

CONCLUSIONS: Many medications thought to be potentially harmful to the geriatric population are not only used alone, but in combination. Clinicians may not be aware of such combinations and their inappropriateness particularly resulting in a Benzodiazepine and Opioid Medication Safety Alert in August 2016. Future implications of this study could be used to determine how many polypharmacy patients experienced first time or recurrent falls during the course of treatment. Additionally, an economic based analysis would help determine the overall cost savings for implementing prevention measures for the elderly demographic.

SPONSORSHIP: Anthem.

V15 Differing Costs Between Episodes of Care Triggered by Abiraterone and Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer in Medicare Supplemental Plans

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BACKGROUND: To improve efficiency and quality of oncology care, CMS implemented the new Oncology Care Model (OCM) based on 6-month episodes triggered by a treatment. Real world evidence regarding episode-based cost of care for metastatic castration-resistant prostate cancer (mCRPC) treatment is lacking.

OBJECTIVE: To analyze costs of episodes of care triggered by oral targeted therapies, abiraterone acetate plus prednisone (ABI+P) and enzalutamide (ENZ), in mCRPC patients, using the OCM framework.

METHODS: Retrospective episode-level cost analysis was conducted using the Truven MarketScan Medicare Supplemental claims database between 1/1/2012-6/30/2016. Following the OCM methodology, eight 6-month episode periods were pre-defined. The first observed ABI+P or ENZ claim in each period was designated as the episode trigger date. Patients were required to have ≥1 diagnosis code (ICD-9/10) for prostate cancer, no end stage renal disease, and ≥6 months of continuous eligibility prior to and post trigger date. The baseline period was the 6 months prior to the trigger date. mCRPC was confirmed by treatment received. Costs were adjusted to 2016 values and winsorized (capped at 5th and 95th percentiles). Patient characteristics and cost were descriptively reported. Comparison of all-cause total episode costs, including and excluding drug costs for ABI+P and ENZ, were conducted using multivariable generalized linear model with gamma distribution and log link function.

RESULTS: A total of 2,423 ABI+P and 1,405 ENZ episodes were identified from the 8 episode periods. Across periods, mean age was 78 years in both cohorts. Mean Quan-Charlson Comorbidity Index score was 7.2 (SD=2.9) in ABI+P and 7.5 (2.7) in ENZ episodes. Mean unadjusted all-cause total episode costs were $70,425 (SD=$27,809) for ABI+P and $80,233 ($36,796) for ENZ. After adjusting for baseline demographics and clinical characteristics, mean episode costs were $70,258 in ABI+P vs. $79,030 in ENZ (adjusted mean difference=$8,772, $P<0.0001$). After excluding ABI+P and ENZ drug costs only, adjusted mean episode costs were $26,840 vs. $33,596 for ABI+P and ENZ triggered episodes, respectively (adjusted mean difference=$6,756, $P<0.0001$).

CONCLUSIONS: Using OCM's episode of care framework, this study found that episodes triggered by ABI+P incurred significantly lower costs compared to episodes triggered by ENZ. However, no causal inference can be made given the cross-sectional nature of the methodology.

SPONSORSHIP: Janssen Scientific Affairs.

V16 The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey

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BACKGROUND: As the U.S. healthcare system shifts from traditional volume-based payments to value-based payments, outcomes-based contracts (OBCs) are gaining popularity among payers and manufacturers. Under this model, stakeholders hope to align drug payment and value to real-world performance metrics (e.g., biomarkers, healthcare resource utilization).

OBJECTIVE: To understand the experiences, perceptions, and needs of payers and manufacturers related to OBCs.

METHODS: The Academy of Managed Care Pharmacy (AMCP) and Xcenda conducted an online survey with payer and manufacturer members. Participants were asked a series of questions regarding their use of OBCs, barriers to implementation, and elements required in establishing successful OBCs. The importance and urgency of specific impediments to successful OBC implementation were also assessed.

RESULTS: The survey was fielded May 12-June 7, 2017, yielding 65 responses (35 payers/30 manufacturers). While a minority of payers/manufacturers had at least 1 OBC in place (20%/33%), a majority had interest in future OBC utilization (71%/63%). Among those with at least 1 OBC in place, 86%/80% of payers/manufacturers had renewed at least 1 OBC in the past 5 years. All payers and 60% of manufacturers with OBCs have included compliance measures. Improvement in clinical outcomes was also common (71%/70%; e.g., reaching set laboratory values goals), and 71%/60% included avoidance of unnecessary medical resource use (e.g., hospitalization, ER visit, etc.). Payers identified the greatest barrier to implementing OBCs as evidence of OBCs reducing pharmacy spending (60%), while manufacturers identified the inability to obtain accurate date/outcome measures (73%) as the major limiting factor. Payers/manufacturers endorsed the use of easily measurable outcomes (91%/100%) as most important in establishing successful OBCs. Manufacturers, and to a lesser extent payers, indicated that regulations and legal issues need to be addressed to make progress in OBC implementation (ie, safe harbor for pre-approval healthcare economic information, clarification of regulations for outside-of-label discussions, anti-kickback statutes to exempt OBCs, and exemption of OBCs for best price requirements).

CONCLUSIONS: Surveyed AMCP members are interested in OBCs and recognize their alignment to societal health goals and healthcare affordability, although actual use of these contracts has been somewhat limited to date. Results from this survey indicate that the potential for OBC use is likely to further rise as barriers/limitations are addressed.

SPONSORSHIP: None.

V18 Status of Current Outcomes-Based Contracting Approaches and Future Thoughts

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Medical Marketing Economics

BACKGROUND: Value-based reimbursement models are gaining momentum in the U.S. Many anecdotal reports have been published regarding the activity of payers and manufacturers engaging in outcomes-based contracting (OBC). However, there is a dearth of research that has systematically explored the current value based contracting landscape and payers' perceptions toward these types of contracts.

OBJECTIVE: The objectives of this study were to examine the current activity of OBC in the U.S., including the prevalence, design, therapy areas of focus, clinical and non-clinical factors that either support or impede adoption, and the activity payers expect to see in the next 2-3 years.

METHODS: An online survey was conducted with 30 pharmacy directors who were a part of a pharmacy and therapeutics committee at a managed care organization. All respondents were responsible for making new drug formulary coverage decisions and were chairing or advising their PandT on such committees. The survey took about 30 minutes to complete.

RESULTS: Respondents reported managing a total of 274,955,428 lives. Of these, 77% were Commercial lives, 15% Medicare, and 8% Medicaid lives. 11 payers reported at least 1 OBC, with measures based on clinical (11) or resource use (8). A spectrum of designs, including treatment guarantees, spend or volume limits, adherence, and real world evidence studies were reported. 11 out of 30 payers have implemented an OBC in one or two disease areas. Two payers reached an agreement, but not implemented; 7 had negotiated, but had not reached agreement; 8 had discussed, but never progressed; and only 2 had never discussed. Most reported that it is too early to evaluate satisfaction with these contracts. Overall, inflammatory conditions (RA, psoriasis, Crohn's), diabetes, and multiple sclerosis were rated as the most attractive for OBC. In the next three years, payers expect a mix of clinical, resource utilization based and guarantee based OBCs having greatest interest. The importance of factors driving interest are overall budget impact, data availability, consensus on measures, and drug prices.

CONCLUSIONS: Results indicate that OBC is still in the early stages, with most payers being exposed, interested, and experimenting. However, payers indicate there are significant barriers to overcome, like the complexity of agreements, manufacturer willingness to accept enough risk, and access to data. About 33% expect OBC to increase in the next 2-3 years, with higher budget areas impacted more so than others.

SPONSORSHIP: None.

V20 Impact of Quality-Based Reimbursement on Physician Practice in Multiple Sclerosis Patient Care

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BACKGROUND: The Medicare Access and Children's Health Insurance Program Reauthorization Act was designed to shift provider compensation from volume-based to value-based reimbursement. Providers will be compensated based on their performance on predefined quality metrics.

OBJECTIVE: To obtain insight from payers and physicians caring for patients with multiple sclerosis (MS) on the impact of quality-based reimbursement initiatives.

METHODS: Eight participants, including MS physicians, pharmacists, and national/regional payer representatives, interacted in a virtual advisory board over 8 days. Participants discussed the effect of quality-based payments on practice and on the provider-payer-pharmaceutical company relationship, and potential solutions to shortcomings in this payment system.

RESULTS: Physicians agreed that bundled payment and/or value-based reimbursement systems will limit their ability to effectively care for MS patients and do not properly reimburse for quality care, particularly for complex cases. Thus, the risk model of payment and electronic health records needs to differentiate patients with complicated or progressive disease to avoid discouraging care of this population. Bundled payments work best in short-term situations where care is standardized, but discourage the use of medications with higher short-term costs and are less effective in the management of complex disease. Quality metrics should be outcomes-based (clinical or patient-reported outcomes [PROs]), identify relapses, and reflect disability and cognitive impairment, but development of meaningful metrics in MS is challenging since many outcomes are not easily quantifiable. Longer timeframes for measuring outcomes could make quality-based payments more successful. Payers noted the quality-based payment structure may help align focus between payers and providers. Payers could provide physicians with data to assist in identifying best practices to improve outcomes and cost. Pharmaceutical companies could provide product data on specific outcomes; provide drug cost transparency; develop new long-term outcome measurements; and provide tools to help physicians track therapy goals, therapeutic success, prescribing, and outcomes, and calculate financial reimbursement.

CONCLUSIONS: Clinical or PRO-based outcomes and longer-term measurement of outcomes may help to capture value in treating complex MS patients. Payers and pharmaceutical companies could provide data and tools to aid physicians in identifying best practices and tracking outcomes and costs.

SPONSORSHIP: Sanofi.

V21 Is a Diabetes Value-Based Insurance Design Associated with Lower Costs?

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BACKGROUND: The CDC states 20% of health care spending is for people with diagnosed diabetes. To encourage optimal DM drug therapy, a value based insurance design (VBID) lowering members' diabetes drugs cost share to zero has been recommended by academics and consultants.

OBJECTIVE: Assess the 2015 annual medical (Med) and pharmacy (Rx) benefits cost associated a population with a DM VBID consisting of insulin at the generic cost share and all DM drugs available for an extended supply of 100 units/tablets/capsules or 34 day supply, whichever is greater, for a single copay compared to a concurrent control group with a standard benefit.

METHODS: This study used integrated Rx and Med claims data to compare 2015 total cost of care. The VBID (intervention) group was the 8,128 DM members who met HEDIS DM diagnosis criteria among 153,330 commercial fully insured members continuously enrolled 2014 to 2015 in a midwest Blue Cross Blue Shield (BCBS) plan that implemented a DM VBID in 2009. The comparison group was a stratified random sample (SRS) of 97,536 members with DM matched 12:1 by one year age group and gender to the VBID population, drawn from a standard benefits control group of 5 million commercially

insured adult members continuously enrolled 2014 to 2015. To assess the background cost differences, a SRS of 32,512 VBID and a SRS of 390,144 standard benefits members without DM were selected, matched 4:1 to the respective DM samples by age and gender. Per member per year (PMPY) total cost of care was calculated by summing all 2015 paid (allowed) amounts, member plus plan paid, medical and pharmacy benefits, without adjustment for rebates or coupons. The 2015 PMPY costs for intervention DM and non-DM were compared to the control DM and non-DM, respectively.

RESULTS: Total cost of care was 7.9% lower in the DM intervention group at $16,086 PMPY compared to the control DM PMPY of $17,465; however, the non-DM intervention group total cost of care was 10.4% lower at $6,257 PMPY compared to the control non-DM of $6,980. Rx cost was 15.3% higher in the DM intervention group at $6,124 PMPY compared to the control DM PMPY of $5,314, while, the non-DM intervention group Rx cost of care was 2.8% lower at $1,498 PMPY compared to the control non-DM of $1,541. Medical benefit cost was 18.0% lower in the DM intervention group at $10,213 PMPY compared to the control DM PMPY of $12,151; however, the non-DM intervention group medical benefit cost was 13.3%lower at $1,189 PMPY compared to the control non-DM of $1,411.

CONCLUSIONS: Within a large commercial fully insured population providing a DM VBID for many years, there was no difference in total cost of care compared to a matched population with standard benefits when the background cost differences were assessed.

SPONSORSHIP: Prime Therapeutics.

General Reviewed Abstracts by ICD-10 Categories
(Presentations: Wednesday, October 18, 12:00 pm-2:45 pm)

A00-B99 Certain Infectious and Parasitic Diseases
(e.g., HIV, Hepatitis C)

A1 Identifying Primary Nonadherence to Prescribed Antibiotics Using Point-of-Sale Data

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BACKGROUND: Primary medication nonadherence (PMN) refers to when patients fail to obtain the first fill of their prescribed medications within an acceptable time period after it was prescribed. Timely initiation of medications is an important issue and critical for effectively treating acute conditions, particularly acute infections.

OBJECTIVE: The main objective of this study was to measure primary nonadherence to antibiotic medications within 21 days antibiotic prescribing using Point of Sale (POS) data from an Integrated Delivery System (IDS). Identification of nonadherence factors (e.g. by patient age, drug class or prescriber characteristics) will potentially be addressed with the development of a "must fill by date" feature into IDS's electronic prescription system for antimicrobials.

METHODS: A retrospective cohort study was conducted using POS data from the McKesson Enterprise RX software in the 24 retail pharmacies owned by the IDS. Patients with ≥1 new antibiotic prescription from January 1, 2016 through December 31, 2016 were eligible. The index date was defined as the date the antibiotic prescription was sent to the pharmacy. Patients were categorized as primary nonadherent if they did not pick up their new antibiotic prescription within 21 days of the index date. Comparisons of those with primary nonadherence with those who obtained their prescription within 21 days were conducted.

RESULTS: A total of 46,873 new antibiotic orders were identified. Of these orders 2,691 (5.7%) were not picked up within 21 days of the order date. The top three antibiotic drug classes identified with a high incidence of primary nonadherence included natural penicillins (8.3%), tetracyclines (8.1%), and urinary anti-infectives (8.1%). There was a greater proportion of patients that were 20-30 years old (10.72%) and 30-40 years old (8.22%) who were classified with primary nonadherence compared to other age groups. Patients who were younger <20 and older >40 had lower nonadherence rates (5.5% and 4.5%, respectively). Primary nonadherent patients had a mean age that was significantly lower (21.38 ± 3.67) than adherent patients (23.77 ± 3.32; t = -10.93, $P < 0.0001$).

CONCLUSIONS: Patient adherence is critical for effectively treating acute infections. In this study, almost 1 in 17 patients (5.7%) failed to pick up their new antibiotic prescription within 21 days. A better awareness of the prevalence and the characteristics associated with primary nonadherence may lead to novel interventions to improve the overall effectiveness of care.

SPONSORSHIP: None.

B1 Cost-Effectiveness of Candidate Adjuvanted Subunit Vaccine for Revaccinating U.S. Adults Previously Vaccinated Against Herpes Zoster

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BACKGROUND: Herpes Zoster (HZ) is a painful and costly reactivation of latent varicella virus in older adults. One vaccine is currently marketed in the U.S. to prevent HZ, Zoster Vaccine Live (ZVL), and a non-live subunit adjuvanted candidate vaccine (HZ/su) is under regulatory review. Clinical literature suggests that waning of ZVL efficacy in previously vaccinated subjects may necessitate revaccination.

OBJECTIVE: To determine the cost-effectiveness of revaccination against HZ: HZ/su versus no vaccine and HZ/su versus ZVL in U.S. adults previously vaccinated with ZVL aged 60+.

METHODS: The ZOster ecoNomic Analysis (ZONA) model is a deterministic Markov model. It followed a hypothetical 1 million (M)-person cohort of U.S. adults aged 60+ previously vaccinated with ZVL (5 years prior) over their remaining lifetimes from the year of revaccination with annual cycle lengths. Three different HZ revaccination strategies were compared: no revaccination, revaccination with ZVL, and revaccination with HZ/su. The primary perspective was societal. Model inputs included residual ZVL efficacy, demographics, epidemiology, vaccine characteristics, utilities and vaccine costs. Costs and quality-adjusted life-years (QALYs) were presented over the lifetimes of the cohort from the year of revaccination and discounted 3% annually. Deterministic and probabilistic sensitivity analyses, along with scenario and threshold analyses, were carried out to explore the robustness of our findings considering uncertainty about model inputs.

RESULTS: The ZONA model estimated that in the 1M-person cohort, revaccinating with HZ/su would reduce disease burden compared to no revaccination, resulting in a gain of 1,633 QALYs at a total societal cost of $96M. This produced an incremental cost-effectiveness ratio of $58,793 per QALY saved. Compared to revaccinating with ZVL, the ZONA model estimated that revaccination with HZ/su would reduce disease burden, resulting in a gain of 1,187 discounted QALYs and a societal cost savings of almost $84M. Sensitivity, scenario, and threshold analyses demonstrated robustness of these findings.

CONCLUSIONS: Revaccination with HZ/su is a cost-effective strategy relative to no revaccination and cost-saving revaccination strategy relative to revaccination with ZVL in U.S. adults aged 60+ who have been previously vaccinated against HZ. Results were robust as demonstrated by sensitivity, scenario, and threshold analyses.

SPONSORSHIP: GlaxoSmithKline Biologicals S.A. funded this study and all related publications.

B2 Real-World Burden of Care for Patients with Chronic Hepatitis C Before, During, and After Treatment with Novel Direct-Acting Antiviral Agents

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BACKGROUND: Chronic hepatitis C (CHC) is associated with substantial morbidity and cost burden. Novel direct-acting antivirals (DAAs) have significantly improved cure rates for CHC.

OBJECTIVE: This study aimed to describe the real-world burden associated with CHC care before, during and after the novel DAA treatment.

METHODS: Adult patients diagnosed with CHC and treated with any novel DAAs (simeprevir, daclatasvir, sofosbuvir, ledipasvir, ombitasvir, paritaprevir, ritonavir, and dasabuvir) were identified from the Clinformatics Data Mart Database (OptumInsight, Eden Prairie, MN) for Commercial and Medicare Advantage beneficiaries (Q1 2011-Q2 2016). Patients were required to have continuous enrollment of at least 6 months prior to and 12 months post DAA initiation. All-cause and CHC-related (i.e., medical services with a CHC diagnosis code) healthcare costs (2016 USD) during the 6 months pre-treatment period, on-treatment period (varied depending on therapy received), and 6 months post-treatment period were assessed.

RESULTS: A total of 5,981 patients were included with mean age 60.4 years (standard deviation [SD] = 9.2) and 62% male patients. 22% of patients received a non-DAA regimen previously. The majority of patients had some liver-related comorbidities prior to the novel DAA treatment, including cirrhosis (42%), nonalcoholic steatohepatitis (23%), splenomegaly (15%), and portal hypertension (14%). Additional common comorbidities were chronic fatigue (45%), cardiovascular diseases (42%), gastroesophageal reflux disease (41%), type 2 diabetes (32%), depression (28%) and kidney diseases (15%). Mean Charlson Comorbidity Index was 3.4 (SD = 2.9). During the pre-treatment, 74% patients had creatinine test, 64% had HCV RNA test, 57% had liver-related imaging test, 38% had HCV genotype test, and 38% had DAA resistance test. Mean treatment duration of novel DAAs was 12.2 weeks (SD = 5.2) with 11% of them contained interferon. All-cause monthly medical costs were similar for the pre-treatment, on-treatment, and post-treatment periods (inpatient: $1,585/$1,830/$1,614; ambulatory: $2,417/$2,161/$2,048, respectively). A reduction in CHC-related monthly medical costs was observed for the post-treatment period (inpatient: $360/$357/$163; ambulatory: $441/$509/$271, respectively).

CONCLUSIONS: The burden for CHC patients before, during, and after novel DAA treatment is still substantial. The implications and unmet needs (e.g., treated with interferon-containing regimens) to stakeholders warrant further investigation.

SPONSORSHIP: AbbVie.

B3 A Specialty Pharmacy Patient Management Program for Government-Sponsored Managed Care Patients Receiving Direct-Acting Antiviral Treatments for Hepatitis C

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PROBLEM DESCRIPTION: Specialty pharmacy patient management programs for hepatitis C have shown improved sustained virologic response (SVR) rates in Hepatitis C, however, the literature is sparse. Since direct-acting antiviral (DAA) treatments entered the market in 2014, managed care has struggled to balance the costs of hepatitis C treatment with the number of hepatitis C positive patients. Ensuring adherence and SVR of recipients of therapy can lower costs by reducing the need for retreatment. The for-profit WellCare Health Plan, Inc., based in Tampa, Florida, has an integrated specialty pharmacy, Exactus, which has developed a patient management program to improve adherence and increase SVR in patients receiving hepatitis C treatment.

GOAL: To improve adherence and to maximize SVR using a specialty pharmacy patient management program at a for-profit government-sponsored managed care company.

PROGRAM DESCRIPTION: Once a prescription is sent to Exactus, a patient profile is created and an initial counseling session is conducted for education on therapy and the disease as well as to ensure adherence. The patient is followed up ten days after initiation of therapy and is then followed monthly. The patient's SVR is collected at week 12 of therapy.

OBSERVATIONS: Since 2014, 1110 patients have been entered into the program. As of June 2017, 981 patients have completed treatment. Of those who completed treatment, 72% provided final viral loads. Total SVR was 90.8% across all of 15 possible regimens treating all 6 genotypes. Of those enrolled in the program, 76 discontinued treatment, or 6.3%. Therefore the overall adherence rate was 93.7%. Adverse drug reactions caused the majority of therapy discontinuations at 32.8%.

FINDINGS/RECOMMENDATIONS: Patient care in the specialty pharmacy, Exactus, resulted in an SVR of 90.8% and an adherence rate of 93.7%. These results suggest that specialty pharmacy patient management of high-cost drugs, like Hepatitis C, may serve as a best practice for other managed care companies and may reduce costs in the long run.

SPONSORSHIP: WellCare Health Plans.

B4 Suboptimal Adherence to Antiretroviral Therapies and Its Association with Patient Characteristics, Healthcare Resource Utilization, Quality of Life, and Loss of Work Productivity Among People Living with HIV/AIDS

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BACKGROUND: Adherence to antiretroviral therapy (ART) is critical to achieving virologic suppression, improving immunologic function, and reducing the risk of drug resistance in people living with HIV/AIDS (PLWHA).

OBJECTIVE: To evaluate adherence, the associated factors, and the impact of suboptimal adherence on healthcare resource utilization (HRU), quality of life (QoL), and loss of work productivity in PLWHA.

METHODS: The study was based on the National Health and Wellness Survey (NHWS, 2016) for HIV. The NHWS was a cross-sectional survey with adults age 18 years and older capturing a variety of health metrics, demographics, treatments and behaviors. The sample population included 409 treated PLWHA, and it was projected to national level using a weighted approach. Adherence was assessed using the Morisky Medication Adherence Scale, 8-item (MMAS-8), and categorized as having Low, Medium, and High adherence using MMAS-8 score <6, $6\sim<8$, and $=8$, respectively. The associations between adherence and patient characteristics, HRU, QoL, loss of work productivity were evaluated and compared.

RESULTS: The projected patient population was 1,282,000. Patients with low, medium, and high adherence accounted for 25.4%, 31.4%, and 43.3% respectively. Compared with patients with medium or high adherence, patients with low adherence were younger (mean age 44.1 vs. 50.5 vs. 55.4 years), more likely single or never married (68.9% vs.

46.9% vs. 40.1%), less likely to be insured (77.2% vs. 95.5% vs. 93.1%; all $P<0.05$), and tended to have lower comorbidity score (Charlson Comorbidity Index=0, 59.5% vs. 60.4% vs. 45.6%; $P>0.05$). They also had lower mental SF-36 score (39.2 vs. 44.8 vs. 45.9), higher work productivity loss (42.6% vs. 21.6% vs. 17.7%), and less general clinic visits (88.9% vs. 98.3% vs. 99.3%; all $P<0.05$). Patients with low and medium adherence had higher ER visit (25.5% vs. 28.3% vs. 13.2%) or hospitalizations (18.0% vs. 15.2% vs. 5.3%; both $P<0.05$) than patients with high adherence.

CONCLUSIONS: Suboptimal adherence among PLWHA remains a serious problem that is associated with poor outcomes. In the current study, more than half of PLWHA at a national level had low to medium adherence. PLWHA with low or medium adherence had higher HRU, poorer QoL and greater loss of work productivity. Efforts to improve adherence, including selecting ARTs that can enhance adherence and reduce the risk of drug resistance, may benefit patients with uncertain adherence and minimize the potential negative consequences.

SPONSORSHIP: Janssen Scientific Affairs.

B5 Persistence Among Treatment-Naive HIV-1 Patients: Single Versus Multiple Tablet Regimen Comparison

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BACKGROUND: Antiretroviral therapy (ART) is a cornerstone of HIV management, working by suppressing viral replication and delaying disease progression. ART is chronically administered, and discontinuation of therapy may result in poor patient outcomes and increased costs associated with switching to more expensive subsequent lines of therapy. Once-daily single-tablet regimens (STRs) have been associated with higher adherence, persistence, and viral suppression when compared to multi-tablet regimens (MTRs).

OBJECTIVE: To (1) assess and update findings regarding persistence with Department of Health and Human Services recommended or alternative STR vs. MTR HIV regimens among treatment naive patients in light of new therapeutic options and (2) assess persistence comparing STRs to other STRs and MTRs to other MTRs.

METHODS: Quintiles IMS's longitudinal prescription claims database (LRx) was used to identify patients with ≥1 claim for any ART from 1/1/2014–5/31/2017, with the first ART claim within the index window (1/1/2015-5/31/2016) serving as the index date. All patients were ≥18 years of age at index, and did not have ART claims during a 12 month washout period. Persistence was evaluated using a <90 days refill gap and reported as mean days on therapy and the proportion of patients remaining on therapy 12 months post-index. Persistence with STRs and MTRs was assessed overall and by regimen using the Kaplan-Meier method. Log-rank test was used to compare persistence.

RESULTS: A total of 39,253 and 10,847 patients on STR and MTR were identified with mean (SD) age of 41.8 (12.8) years for STR patients (77.1% male) and 43.4 (12.3) years for MTR patients (70.8% male). Patients initiating with a STR had more days on therapy (mean [SD]: 419.0 [1.47] vs. 327.0 [2.51]; $P<0.0001$); more STR patients remained on therapy at 12 months (49.7% vs. 36.1%) than those on MTRs.

CONCLUSIONS: This study reinforces previous studies which suggested better persistence with STR versus MTR HIV regimens. In light of new therapeutic options, persistence in this commercially insured population was highest with STRs and lowest among patients using MTRs with a boosted third agent. To maximize the benefits of increased treatment durability, it's important to consider STRs versus MTRs to improve persistence when managing HIV patients.

SPONSORSHIP: Gilead Sciences.

B6 Real-World Health Plan Data Analysis: Key Trends in Medication Adherence and Overall Costs in Patients with HIV

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BACKGROUND: The CDC estimates that more than 1.2 million people in the U.S. are living with human immunodeficiency virus (HIV). Optimum care for these individuals requires adherence to effective antiretroviral therapy. The introduction of single tablet regimens (STR) has resulted in improved adherence and decreased healthcare costs and hospitalizations for patients with HIV compared to existing multiple tablet regimens (MTR). However, the relationship between adherence and healthcare costs may be more complicated than previously thought.

OBJECTIVE: Determine key trends in adherence and costs of care for patients with HIV stratified by length of follow-up.

METHODS: This retrospective study analyzed medical and pharmacy claims data from 1/1/2007-6/30/2016 for commercially insured patients continuously enrolled for 6 months prior to the index date and at least 15 months after. The index date was the first medical claim with a diagnosis of HIV or an HIV antiretroviral medication. Qualifying patients were ≥18 years old with ≥2 paid HIV medical claims. Each patient was categorized based on pill burden (STR or MTR), adherent (defined as ≥95% proportion of days covered [PDC]), and divided into 2 cohorts based on length of available follow-up: <3 years (cohort 1); ≥3 years (cohort 2). Descriptive statistics were generated with mean provided for continuous variables.

RESULTS: A total of 1,698 patients met inclusion criteria; 686 and 1,012 had <3 and ≥3 years of follow-up data respectively (mean 2.1 vs. 4.7 years,). STR patients represented 47% and 37% of the treated subjects in cohorts 1 and 2, respectively. More patients on STR achieved ≥95% adherence than MTR patients (cohort 1, 53% vs. 39%; cohort 2, 61% vs. 45% $P<0.001$). In both cohorts, non-adherent patients had numerically higher mean annual medical costs but significant for cohort 2 only (cohort 1 $10,572 vs. $9,474; $P=0.819$ and cohort 2, $8,224 vs. $3,097; $P<0.001$). However, there was significant savings in mean annual inpatient costs between the adherent and non-adherent in both cohorts (cohort 1, -$2,525; $P<0.001$ and cohort 2, -$815; $P<0.001$).

CONCLUSIONS: Patients on STR were more adherent than patients on MTR regardless of the length of follow-up. Better adherence was associated with significant inpatient cost savings. The relationship between adherence and total medical costs is more nuanced than previously reported depending on the follow-up period. Results suggest further examination of the time-dependency of improved adherence to improved clinical and cost outcomes.

SPONSORSHIP: ViiV Healthcare.

B7 Fracture Rates in U.S. Veterans with and Without HIV: A Cohort Study, 2000-2016

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BACKGROUND: Human immunodeficiency virus (HIV) has been associated with an increased risk of fractures in select studies.

OBJECTIVE: Using a national cohort of HIV infected veterans and their non-HIV matched controls, we evaluated the association between HIV and osteoporotic fractures within the Veteran's Affairs (VA) Administration system.

METHODS: This study used claims from the VA system from Jan 2000-Dec 2016. Data were extracted from the VA Informatics and Computing Infrastructure (VINCI). Cases include all veterans with an ICD-9/10 for HIV who had at least one prescription for a complete antiretroviral therapy (ART) regimen. A complete ART regimen was defined as 2 nucleoside/nucleotide reverse transcriptase inhibitors plus a third agent (e.g., a non-nucleoside reverse transcriptase inhibitor). Two non-HIV controls were exact matched on race, sex, month and year of birth. Both HIV cases and their controls were followed until the earliest of the following: first osteoporotic fracture; last date of VA activity; death; or Dec 31, 2016. The outcome was the first osteoporotic fracture occurring after index, identified based on diagnosis codes. The relative risk (RR) and 95% confidence intervals were estimated from a multivariable Poisson regression model. Models were adjusted for demographic factors and comorbidities.

RESULTS: A total of 26,526 HIV patients met all study criteria and were matched to non-HIV controls (n = 53,052). The average age was 49.3 years, 38% were black, 32% were white, and 97% were male for both the HIV and control cohorts. The HIV cohort had a higher average Charlson Comorbidity Index, more patients with hepatitis C, drug/alcohol, mental health and smoking history, but fewer with diabetes. In the unadjusted model, HIV was associated with a 3-fold increased rate of fractures compared to the matched controls (RR 3.12, 95% CI: 2.82-3.46). After controlling for baseline covariates, HIV patients had a 38% increased risk of fractures compared to the non-HIV controls (RR 1.38 95% CI: 1.23-1.56).

CONCLUSIONS: This study documents fracture risk within a national cohort of HIV patients compared to non-HIV controls within the VA system, the largest single provider of care to HIV-infected individuals in the United States. Fracture risk is significantly increased in HIV patients compared to matched non-HIV controls, which is consistent with findings published in commercially insured HIV patients. Results suggest that the potential for fracture risk should be considered when evaluating therapeutic options for HIV patients.

SPONSORSHIP: Gilead Sciences.

C00-D49 Neoplasms *(e.g., Breast Cancer, Lung Cancer, GIST, Melanoma, CML, CLL, Multiple Myeloma)*

C1 Advanced Gastric Cancer: A Systematic Review of Cost-Effectiveness Analyses of Current Therapies

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BACKGROUND: Gastric cancer (GC) is the third most common cause of cancer death worldwide. In the United States (U.S.), ~28,000 new cases and ~11,000 deaths are estimated to occur in 2017. GC often presents as advanced disease upon diagnosis, comprising about 40% of newly diagnosed case in the U.S., and 20% in Japan.

OBJECTIVE: To summarize and evaluate published cost-effectiveness models of current treatments for advanced gastric cancer (aGC).

METHODS: A systematic literature review was conducted, searching MEDLINE (2007-2017), grey literature, public-use databases/websites, and conference proceedings. English-language studies of cost-effectiveness analyses that evaluated treatments in aGC were included.

RESULTS: Twelve economic models were identified and were clinically and methodologically heterogeneous. Models were from the U.S. (N = 2) and Asian (N = 10) perspectives. All models reported cost/quality-adjusted life-year metrics, seven used a payer perspective, two reported a societal perspective, while three studies did not report perspective; very few studies reported indirect costs. In two studies evaluating first-line (1L) therapy, both mFOLFOX7 and ECX (epirubicin/cisplatin/capecitabine) were cost-effective compared to FOLFIRI. Irinotecan in 2L was found to be cost-effective compared to docetaxel, paclitaxel, ramucirumab (RAM), paclitaxel + RAM, or palliative care. Another study found 2L chemotherapy in elderly (≥ 70 y.o) aGC patients to be an optimal strategy compared to best supportive care (BSC). RAM + paclitaxel in 2L compared to paclitaxel alone was not found to be cost-effective from a U.S. perspective, but had a favorable cost-effectiveness ratio (ICER) from a Japanese perspective. Three models reported an ICER for trastuzumab vs. chemotherapy-alone in HER2-positive aGC exceeding commonly-used, willingness-to-pay thresholds. Three models evaluated apatinib in patients who progressed on ≥ 2 lines of chemotherapy: one found it cost-effective compared to BSC, while the remaining models did not find apatinib cost-effective compared to either chemotherapy or BSC.

CONCLUSIONS: Diverse results were observed across the economic models evaluating treatments in aGC, likely reflecting the heterogeneous characteristics of the various trials and modeling methods used. Cost-effectiveness analyses alone are not sufficient for assessing the value of treatments for aGC patients in the U.S. Decision-making in this patient population requires a holistic evaluation of treatment efficacy, safety, and total cost of care.

SPONSORSHIP: Bristol-Myers Squibb.

C2 The Economic Burden of Microsatellite Instability-High Colorectal Cancer and Metastatic Colorectal Cancer Patients Treated with Pharmacotherapy: A Systematic Review

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BACKGROUND: Colorectal cancer (CRC) is the third most commonly diagnosed cancer in the United States (U.S.). More than 50% of CRC patients eventually develop metastatic CRC (mCRC), and 4-5% of mCRC patients have microsatellite instability-high (MSI-H) tumors. As new therapies emerge, it is important to understand the economic burden associated with pharmacotherapy.

OBJECTIVE: To summarize the economic burden in patients with MSI-H CRC and mCRC who are treated with pharmacotherapy.

METHODS: A systematic literature review was conducted, searching MEDLINE (2007-2017), grey literature, public-use databases/websites, and conference proceedings. Full-text studies of U.S. patients with MSI-H or mCRC who received pharmacotherapy and which reported on economic burden were included. Economic burden was comprised of direct and indirect costs (adjusted to June 2017 US$) and healthcare resource use (HCRU).

RESULTS: The search yielded 497 non-duplicate citations. Following title/abstract and full-text screening, no MSI-H CRC studies met inclusion criteria (most citations focused only on testing/identifying MSI-H CRC). Fifteen mCRC studies were included; the majority analyzed claims databases from the payer and patient

perspectives. Mean annualized total cost/ patient are almost double in mCRC ($155,329) vs. non-metastatic CRC ($78,812), $P<0.01$. Patients treated with antineoplastics experience a higher range of mean cost/ patient ($96,885-$142,330) 12-months from diagnosis compared with untreated patients ($50,110-$56,306). For mCRC patients receiving pharmacotherapy, mean cost/patient steadily increased from 2000-2009. Studies evaluating HCRU were heterogeneous, but revealed high utilization in mCRC patients. One study found an average of 2.7 emergency department visits and 2.4 inpatient admissions from diagnosis until end of variable follow-up. As patients received subsequent lines of therapy, the mean number of office visits and outpatient services decreased: first-line therapy (n=504) was associated with 29 visits and 9.8 services, while patients on fourth-line therapy (n=81) had 19.9 visits and used 6.1 services.

CONCLUSIONS: While published research assessing the impact of pharmacotherapy on the economic burden of MSI-H CRC is evolving, patients with mCRC reportedly experience substantial economic burden. As the pharmacotherapy landscape to treat mCRC and MSI-H mCRC continues to evolve, there is a need to better understand the economic burden associated with this population to optimize health outcomes.

SPONSORSHIP: Bristol-Myers Squibb.

C3 Large Retrospective Study of Outcomes and Supportive Care Use in Metastatic Pancreatic Adenocarcinoma Patients Treated with First-Line Nab-Paclitaxel+Gemcitabine and FOLFIRINOX

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BACKGROUND: Both nab-paclitaxel+gemcitabine (nab-P+G) and FOLFIRINOX (FFX) have demonstrated improved overall survival (OS) vs. gemcitabine as first-line (1L) treatment (tx) for metastatic pancreatic adenocarcinoma (mPAC), yet no comparative data exists. Differing toxicity profiles can impact tx selection and economics of care.

OBJECTIVE: We previously reported time to tx failure (TTF) and OS in a real-world study of 1L nab-P+G or FFX patients (pts). We now report toxicity and supportive care use.

METHODS: This retrospective study used an electronic health record (EHR) database and claims data from the U.S. Oncology Network. Pts had newly diagnosed stage IV mPAC and received 1L nab-P+G or FFX from 04/2013-10/2015 with follow-up to 01/2016. Eligibility required ≥3 doses of nab-P or ≥2 doses of fluorouracil and excluded pts on clinical trial or with other primary cancers. Categorical variables were compared with chi-squared tests. TTF and OS were assessed with the Kaplan-Meier method. Multivariable Cox regression analyses were performed.

RESULTS: Among 2,901 mPAC pts identified, 255 nab-P+G and 159 FFX pts with 1L tx met eligibility. Median age was 68 yrs for nab-P+G and 61 yrs for FFX ($P<0.0001$). ECOG PS was 0-1 in 77% of nab-P+G pts and 91% of FFX pts ($P=0.0004$). There was no significant difference in median TTF or OS for nab-P+G vs FFX (TTF 3.7 vs. 4.3 mo, log-rank $P=0.25$; and OS 9.8 vs. 11.4 mo, log-rank $P=0.38$). Cox multivariable analyses revealed no significant difference by regimen, age, or gender; ECOG PS of 2+ vs. PS 0 significantly increased risk of death (HR 2.4, $P<0.05$). In a sub-group of PS 0-1 pts, OS was similar among nab-P+G and FFX pts (12.1 vs. 11.4 mo, log-rank $P=0.68$). Rates of non-hematologic toxicity were similar between groups, and no difference was observed in use of antibiotics, nausea, or pain medications. Neutropenia occurred in 11.3% of FFX and 9.8% of nab-P+G pts ($P=0.91$). Pegfilgrastim (PGF) was used in 43% of FFX and 13% of nab-P+G pts ($P<0.0001$); red blood cell growth factor use was 13% for FFX and 17% for nab-P+G pts ($P=0.27$).

CONCLUSIONS: TTF and OS were not significantly different in 1L nab-P+G and FFX pts. nab-P+G pts were older with worse PS. Toxicities appeared similar, yet more PGF use was observed in pts receiving FFX.

SPONSORSHIP: Celgene.

C4 Changes in Incidence of Metastatic and Recurrent Colorectal Cancer Trends Stratified by Stage, Line of Therapy, and High Microsatellite Instability in the United States from 2017 to 2021

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BACKGROUND: Colorectal cancer (CRC) is the third most commonly diagnosed cancer and fourth leading cause of cancer deaths in the U.S. Metastatic CRC (mCRC) or recurrent CRC is associated with poor survival. Population-based estimates of mCRC, recurrent CRC, and their changes over time will help quantify burden of illness.

OBJECTIVE: Estimate 5-year future incidence/prevalence of mCRC and recurrent CRC in the U.S. by gender, age, and stage at diagnosis; and estimate population distribution across systemic lines of therapy (LOTs) and with high level of microsatellite instability (MSI-H).

METHODS: Colon and rectal cancer incidence rates were calculated from SEER-18 cancer registries, using first matching record for patients age ≥20 years diagnosed from 2004-2014. Estimated incidence/prevalence was calculated by multiplying tumor-, gender-, stage-, and age-specific incidence rates/prevalence proportions by corresponding gender- and age-specific U.S. population estimates for 2017-2021. Trend analyses of historical incidence rates were used to estimate CRC incidence. Five-year recurrence rates by stage were applied to prevalent CRC estimates. Combined incident mCRC (stage IV) and recurrent CRC estimates were stratified by systemic LOTs and MSI-H status.

RESULTS: While overall incidence of CRC is estimated to decline from 2017-2021 (132,192 to 128,826), incidence of mCRC increases by 3.23% (16,028 to 16,546) for males and 0.88% (13,566 to 13,685) for females. Among females, increases in 20-64 year olds is 1.47% (5,635 to 5,718), and 0.45% (7,931 to 7,967) in 65+, while for males an expected increase is 3.23% both in 20-64 year olds (7,392 to 7,631) and 65+ (8,636 to 8,915). Incidence of recurrent CRC across all stages at diagnosis increases by 7.92% (18,078 to 19,509) for females and 8.99% (19,061 to 20,774) for males; estimates increase 0.65% (15,771 to 15,873) in 20-64 year olds and 14.24% (21,368 to 24,410) in 65+. Combined mCRC and recurrent CRC incidence is expected to increase from 66,730 to 70,512 (5.67%), with an increase of 6.14% across all systemic LOTs; 3L treated patients increasing from 10,574 to 11,223 (6.14%) over 5 years; those with MSI-H status treated in the 3L increasing from 529 to 561 (6.05%).

CONCLUSIONS: Despite decreases in overall CRC incidence (stages I-IV), it is estimated that incidence of mCRC and recurrent CRC, and use of all systemic LOTs will increase over the next 5 years. The increasing incidence over time supports the need for novel therapies and continued research efforts in this patient population.

SPONSORSHIP: Bristol-Myers Squibb.

C5 Cost-Effectiveness of Ceritinib in Previously Untreated ALK-Positive Non-Small Cell Lung Cancer in the United States

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BACKGROUND: Ceritinib (Zykadia) has been approved in the U.S. for anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC). A phase III randomized trial (ASCEND-4) has shown ceritinib to effectively improve progression-free survival (PFS) vs. chemotherapy for untreated ALK+ metastatic NSCLC. Therefore, it is important to understand the economic value of ceritinib compared with that of existing treatments in the untreated population.

OBJECTIVE: To assess the cost-effectiveness of ceritinib compared to existing treatments as 1st-line treatment for ALK+metastatic NSCLC from a U.S. third-party payer's perspective.

METHODS: A partitioned survival model with three health states (stable, progressive, and death) was used to evaluate costs and effectiveness associated with 1st-line ceritinib compared to crizotinib and chemotherapy (platinum+pemetrexed with pemetrexed maintenance) over a lifetime. Efficacy inputs (PFS, overall survival) of ceritinib were estimated using data from a phase III randomized trial (ASCEND-4) and were extrapolated beyond the trial period using parametric survival models. Relative efficacy of ceritinib vs. crizotinib was estimated using matching-adjusted indirect comparison based on ASCEND-4 trial data and published PROFILE 1,014 results. Relative efficacy of ceritinib vs. chemotherapy was obtained from ASCEND-4. Drug acquisition, administration, adverse events, and medical costs associated with each health state were obtained from publicly available databases or literature and inflated to 2016 US$. Treatment-specific utilities for the pre-progression state were derived from trial and utility for progressive state was obtained from literature. Incremental costs per quality-adjusted life year (QALY) and life years (LY) gained were estimated comparing ceritinib vs. each comparator. Deterministic and probabilistic sensitivity analyses were performed.

RESULTS: In the base case, 1st-line treatment with ceritinib was associated with 3.28 QALYs, and total direct costs of $299,777 over 20 years. Over the same time horizon, 1st-line crizotinib and chemo were associated with 2.73 and 2.41 QALYs, and $263,172 and $228,184 total direct costs, respectively. The incremental cost per QALY gained was $66,064 comparing ceritinib vs. crizotinib and $81,645 comparing ceritinib vs. chemotherapy. Results were robust to sensitivity analyses.

CONCLUSIONS: Compared with standard of care, ceritinib offers a cost-effective option in the treatment of previously untreated ALK+ metastatic NSCLC in the U.S.

SPONSORSHIP: Novartis Pharmaceuticals.

C6 Healthcare Cost in Patients with Advanced Non-Small Cell Lung Cancer and Disease Progression on Targeted Treatment in a Real-World Setting

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BACKGROUND: Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) improve outcomes in patients (pts) with EGFR mutation-positive, advanced non-small cell lung cancer (NSCLC). However, resistance to EGFR TKIs does develop and leads to disease progression. Characterizing cost of care is necessary to understand the economic burden in pts with NSCLC receiving EGFR TKIs during initial treatment and following progression.

OBJECTIVE: To assess cost of care and its contributing components during treatment with a first- or second-generation TKI and following progression, and identify areas of unmet need.

METHODS: A retrospective analysis was conducted of medical records from 10 U.S. community oncology practices (most pts from south USA). Eligible pts had advanced NSCLC (stage IIIB/IV) diagnosed between 1/1/2008 and 1/1/2015, were treated with the TKI erlotinib or afatinib either first or second line, and had progression per treating clinician's assessment. Monthly Medicare-paid costs were evaluated during TKI therapy and post progression.

RESULTS: The study included 364 pts (77.7% Caucasian, 17.3% African American, mean age 66.3 years, 64.0% treated with first-line TKI). The total mean monthly cost during TKI therapy was $20,106 (SD $31,724), which was composed largely of hospitalization and anti-cancer therapy costs (47.0% and 42.4%, respectively). Following progression (data available for 316 pts), the total mean monthly cost was $19,274 (SD $35,639). The cost was higher in the 76.3% of pts who received anti-cancer therapy post progression than in the 23.7% who did not ($20,490 vs. $15,364, respectively, $P<0.001$). Among pts who received anti-cancer therapy, anti-cancer therapy ($11,198; SD $32,285) and hospitalization ($5,805; SD $13,546) represented 54.7% and 28.3% of the total mean monthly cost, respectively. Among pts who did not receive anti-cancer therapy, hospitalization ($13,829; SD $38,713) represented 90.0% of the total mean monthly cost (between-group difference in hospitalization not statistically significant).

CONCLUSIONS: The cost of care during TKI treatment and following progression appeared to be similar and was largely attributed to hospitalization and anti-cancer therapy. Notably, almost one-fourth of pts did not receive anti-cancer therapy post progression. Among pts not receiving anti-cancer therapy, hospitalization was the largest cost contributor, highlighting the need for additional effective targeted therapies that could prevent hospitalization after progression on first- or second-generation EGFR TKIs.

SPONSORSHIP: AstraZeneca.

C7 Economic Impact of Adding Brigatinib as a Second-Line Therapeutic Option for Anaplastic Lymphoma Kinase-Positive Metastatic Non-Small Cell Lung Cancer in the United States

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BACKGROUND: With the recent inclusion of brigatinib (BRG) in NCCN Guidelines for the treatment of crizotinib (CRZ)-resistant, anaplastic lymphoma kinase–positive (ALK+) metastatic non-small cell lung cancer (mNSCLC), there is a need to assess the potential impact on healthcare budgets.

OBJECTIVE: To model the economic impact on U.S. health systems of adding BRG as a second-line (2L; post-CRZ) therapeutic option for ALK+ mNSCLC.

METHODS: A Markov model was built using a partition survival framework with 3 health states (progression-free, progression, and death), a 12- or 24-mo time horizon, and monthly cycles. The model compared current therapeutic options, ceritinib (CER) and alectinib (ALEC; 64% and 36% of therapy mix, respectively) with future therapeutic options, CER, ALEC, and BRG (29%, 18%, and 53% of therapy mix, respectively, assuming adoption of BRG at steady state). Time spent in

each health state was determined by the area under the OS and PFS parametric curves. Patient-level data were estimated using published Kaplan-Meier curves from pivotal trials of CER (NCT01685060; median follow-up 11.3 mo) and ALEC (NCT01801111, median follow-up 21 mo). For BRG (180 mg qd with 7-d lead-in at 90 mg), patient-level data from the ALTA trial in ALK+ NSCLC patients with disease progression on CRZ (NCT02094573; median follow-up 11.0 mo) were used. Costs were based on 2017 WAC and CMS fees and included only direct medical costs borne by payers (e.g., therapy, adverse events, therapy initiation, monitoring, and management of progression).

RESULTS: The probability of PFS with CER, ALEC, and BRG was 11%, 41%, and 62%, respectively, at 12 mo and 0%, 19%, and 24%, respectively, at 24 mo. Assuming steady-state adoption, including BRG in the treatment mix for 12 and 24 mo resulted in the incremental impact of −$4,712 and $5,148 per patient per year (PPPY), respectively, and −$0.002 and $0.002 per member per mo (PMPM), respectively. Savings per mo without progression were $4,463 and $3,856 after 12 and 24 mo, respectively, due to increased PFS. PPPY and PMPM results were most sensitive to therapy cost, dose intensity, therapy mix, and post progression costs; other inputs had minimal effect. A probability sensitivity analysis showed introducing BRG had a >99% chance of keeping costs <$0.01 PMPM, suggesting cost savings or neutrality.

CONCLUSIONS: Introducing BRG as a 2L (post-CRZ) treatment option for ALK+ mNSCLC may be budget neutral, or potentially cost saving, in the context of delaying disease progression.

SPONSORSHIP: ARIAD Pharmaceuticals.

C8 Cost-Effectiveness of Afatinib Versus Gefitinib in the First-Line Treatment of Metastatic NSCLC Patients with EGFR Exon 19 Deletion or Exon 21 Substitution (L858R) Mutations

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BACKGROUND: LUX-Lung 7 was a randomized multicenter trial comparing two FDA-approved EGFR-targeting tyrosine kinase inhibitors—afatinib and gefitinib. Study findings showed that afatinib had improved efficacy over gefitinib in several clinical endpoints including progression-free survival (PFS).

OBJECTIVE: The objective of this study was to assess the cost-effectiveness of afatinib versus gefitinib from a U.S. healthcare system perspective, based on the results of LUX-Lung 7.

METHODS: A partitioned survival model was developed consisting of "progression-free disease", "progressive disease", and "death" health states. Survival curves were estimated by fitting parametric models to PFS and overall survival empirical data from LUX-Lung 7. Costs included drug, adverse reaction, and additional disease management costs. Utility values were applied based on health status. Inputs were derived from published literature, public datasets, and clinical trial data. The model calculated life-years (LYs), quality-adjusted life-years (QALYs), and total costs per patient. Costs and outcomes were calculated over a patient's lifetime and discounted at 3% per annum. Incremental cost-effectiveness ratios (ICERs) were then calculated. One-way and probabilistic sensitivity analyses (PSA) were conducted to characterize parameter uncertainty.

RESULTS: Afatinib patients accrued 0.29 more LYs and 0.22 more QALYs than those treated with gefitinib. The incremental cost per patient was $29,203 higher with afatinib owing to the increased PFS associated with afatinib treatment. The ICERs were $99,142 per LY gained and $130,136 per QALY gained, respectively. This is below the widely accepted cost-effectiveness threshold of $150,000 per QALY gained. One-way sensitivity analysis showed that results were most sensitive to changes in drug costs and progression-free disease management costs. In the PSA, the ICER was below the $150,000 per QALY gained threshold in 55% of simulations conducted.

CONCLUSIONS: Afatinib, as a first-line therapy for metastatic NSCLC with EGFR exon 19 deletion or exon 21 substitution (L858R) mutations, is cost-effective compared to gefitinib at a threshold of $150,000 per QALY gained.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.

C10 Temporal Trends in Adverse Event Costs with Nivolumab-Ipilimumab Combination Therapy, Nivolumab Monotherapy, and Ipilimumab Monotherapy for Unresectable or Metastatic Melanoma

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BACKGROUND: Nivolumab and ipilimumab were approved by the FDA for the treatment of unresectable or metastatic melanoma as combination therapy and as monotherapies.

OBJECTIVE: This study describes the per-patient adverse event cost trends of nivolumab-ipilimumab combination therapy, nivolumab monotherapy, and ipilimumab monotherapy over 2 years.

METHODS: Patient-level data of the CheckMate-067 clinical trial were used to assess the frequency of all-cause and treatment-related adverse events associated with nivolumab-ipilimumab combination therapy, nivolumab monotherapy, and ipilimumab monotherapy. Adverse events reported between first dose and 30 days after the last dose were included. Adverse event unit costs were obtained from a targeted literature review as well as the Healthcare Cost and Utilization Project (HCUP) database and were inflated to 2017 USD. For each quarter year, average monthly adverse event costs per patient were calculated as total adverse event cost incurred divided by the sum of person-months at risk during the quarter. Average monthly costs over 2 years were calculated for each treatment.

RESULTS: For nivolumab-ipilimumab combination therapy, nivolumab monotherapy, and ipilimumab monotherapy, the average monthly all-cause adverse event costs per patient over the first quarter were $6,488, $1,952, and $3,625, respectively. By the third quarter, the average monthly all-cause adverse event costs per patient fell by 90% to $670 for nivolumab-ipilimumab combination therapy, by 46% to $1,062 for nivolumab monotherapy, and by 82% to $677 for ipilimumab monotherapy. For the remaining five quarters, monthly all-cause adverse event costs stayed relatively constant ranging from $603-1,072, $521-1,062, and $257-995 per patient for nivolumab-ipilimumab combination therapy, nivolumab monotherapy, and ipilimumab monotherapy, respectively. Monthly treatment-related adverse event costs followed similar temporal trends.

CONCLUSIONS: For unresectable or metastatic melanoma, the majority of adverse event costs for first-line treatment with nivolumab-ipilimumab combination therapy occur at the beginning of treatment; however, these costs were comparable to those of nivolumab and ipilimumab monotherapies from the third quarter onwards. These results show that the cost associated with the adverse-event burden to achieve the additional efficacy is minimal.

SPONSORSHIP: Bristol-Myers Squibb.

C11 Historic Treatment Patterns in Patients with Merkel Cell Cancer in a Large U.S. Commercially Insured Population

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BACKGROUND: Merkel cell carcinoma (MCC) is a rare skin cancer, occurs frequently in the elderly, exhibits aggressive clinical features and is associated with a poor prognosis. Real-world data on treatment patterns in MCC in community settings are limited.

OBJECTIVE: Characterize treatment patterns for patients newly diagnosed with MCC in the U.S. in clinical practice.

METHODS: Newly diagnosed MCC patients were identified based on ICD-9 codes for MCC from 1/7/2010 to 31/12/2014 in MarketScan administrative claims databases. Patients were required to be continuously enrolled for 6 months before the index diagnosis with no gap, not to have any enrollment gap over 30 days during follow-up and followed from index date to end of enrollment, inpatient death, or end of study period (31/12/2014).

RESULTS: 2,355 MCC patients met selection criteria: average age at diagnosis was 68.8 years, 60.3% were >65 years and 60.3% male. 12 patients were <18 years. Tumor site at index were other sites (31.0%), face (25.3%) and upper limbs (14.3%). 2,177 patients had no enrollment gaps during follow-up, of these 35.2% received only surgery, 21.3% surgery and radiation, 14.4% chemotherapy, surgery and radiation, 14.7% of patients had no recorded treatment, 8% surgery and chemotherapy, 3.7% only chemotherapy, 1.4% chemotherapy and radiation, and 1.4% radiation only. Out of the 2,177 patients 599 (27.5%) patients received first line (1L) chemotherapy, and of these 1L patients 178 (29.7%) also received second line (2L), 38 (6.3%) received third line (3L), and 12 (2%) patients received four or more lines (>4L). Common 1L regimens were etoposide (39.7%), carboplatin (32.7%) and cisplatin (14.7%), and for 2L they were carboplatin (28.7%), etoposide (27.0%) and fluorouracil (14.0%). Common 3L therapies were similar to 1L and 2L therapies. The more lines of therapy received, the shorter the duration of the line (average duration (days): 1L=105; 2L=98; 3L=83; >4L=42).

CONCLUSIONS: This study provides new insights into clinical care of MCC in a managed care setting. More patients received chemotherapy than expected seeing that this treatment option is indicated for metastatic patients. Use of similar chemotherapies across lines of treatment reflects limited options for patients, and the shorter duration of each line suggests an urgent need for new and alternative treatment options that are effective, tolerated and durable. Immunotherapy may provide oncologists with additional treatment options for these patients.

SPONSORSHIP: Merck KGaA and Pfizer.

C12 A Retrospective Claims Analysis of Baseline Demographic, Clinical Characteristics, and Treatment Patterns Among Women with HR+/HER2-Advanced/Metastatic Breast Cancer Receiving Palbociclib

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BACKGROUND: Palbociclib is a cyclin dependent kinase (CDK) 4/6 inhibitor approved in the United States in combination with aromatase inhibitors (AIs) or fulvestrant for hormone receptor positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer (ABC or MBC). To date, palbociclib has been prescribed to over 60,000 patients in the United States.

OBJECTIVE: We examined the demographic and clinical characteristics, and treatment dosing patterns of women initiating palbociclib (PAL) in real-world settings.

METHODS: This is a retrospective cohort study utilizing the Truven Heath MarketScan (TM) and Optum Clinformatics (OC) administrative claims databases to characterize baseline demographic, clinical characteristics, and treatment dosing patterns of women with presumed HR+/HER2- MBC initiating PAL in combination with an AI or fulvestrant from February 2015 through June 2016. The index date is defined as the first prescription for PAL with concomitant medication (i.e., AI or fulvestrant) evaluated within ±30 days of PAL; therefore, patients may have received more than one concomitant medication during this time period.

RESULTS: Overall, 2,266 women who met selection criteria were identified having a prescription for PAL. Mean age (years) at PAL initiation was 61 years old (27.7% were age 18-54, 35.2% were age 55-64, 21.4% were age 65-74 and 15.7% were age ≥75) and 63% enrolled in a Commercial plan. Mean follow-up was 6.6 mo (SD=4.5). Of those initiating PAL with endocrine therapy, 71.7%, 7.3%, 7.7%, and 29.4% received in combination with letrozole, anastrozole, exemestane, and fulvestrant, respectively. 88.1% initiated with PAL 125 mg, 8.6% at 100 mg and 3.4% at 75 mg. Any dose reductions were observed in 27.1% of patients (25.2% of patients receiving 125 mg). A total of 31.3% of patients received chemotherapy before PAL initiation. Interim results are presented; data from an additional 9 months of follow-up (through March, 2017) are pending.

CONCLUSIONS: Real-world data for palbociclib post approval within two administrative claims databases show 88.1% of patients initiate PAL 125 mg corresponding to the recommended U.S. prescribing information starting dose with a lower proportion of patients having a dose reduction compared to the PALOMA trials. Additionally, over 70% of patients initiated PAL concomitantly with letrozole, which corresponds with the initial approval. Final results with additional follow-up will be presented at conference.

SPONSORSHIP: Pfizer Oncology.

C13 What Is the Cost of Treating HER2 Metastatic Disease?

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BACKGROUND: Up to 1 in 4 women with HER2+ early breast cancer will still develop metastatic breast cancer (mBC) despite current advances in treatment. As new agents and combination regimens become available in the early stage adjuvant setting for the treatment of HER2+ breast cancer, it is important to understand the economic impact of preventing metastatic disease. The costs of treatment of mBC in the era of dual HER2 therapies have not been thoroughly evaluated.

OBJECTIVE: This study evaluated the costs of mBC among patients who received HER2 targeted agents.

METHODS: The study included adults with diagnosis of mBC and received HER2 targeted agents (trastuzumab, ado-trastuzumab emtansine, pertuzumab or lapatinib) from 2007-2014 in the Optum U.S. claims database. Index date was the date of the first systemic BC therapy after metastatic diagnosis. Total health care costs were reported for the first 12 months post-index date, comprised of both medical and pharmacy costs. Medical costs were reported by sites of service: physician/provider office, hospital outpatient, hospital inpatient, emergency department or other. Drug therapies provided in a facility

setting were captured as part of the medical costs. Pharmacy costs captured all prescriptions filled through the pharmacy benefit.

RESULTS: 1,121 mBC patients received HER2 targeted agents. Average total healthcare cost per patient in the first year following diagnosis of metastatic HER2 breast cancer was $168,248 (median $143,580, standard deviation $116,501). Average medical costs ($158,417) represented 94% of total costs, of which 50% ($78,638) was related to hospital outpatient care, 39% ($61,097) was delivered in physician/provider facility. Inpatient hospitalizations comprised 10% ($15,541) of medical costs. Pharmacy costs accounted for 6% ($9,831) of total healthcare costs.

CONCLUSIONS: The total health care cost of treating HER2 positive breast cancer in the first year of metastatic diagnosis is high. Reducing recurrences with better treatments in the adjuvant setting may be important in alleviating the economic burden associated with metastatic disease in HER2 positive breast cancer.

SPONSORSHIP: Genentech.

C15 Budget Impact of Introducing Avelumab as a Second-Line Treatment for Locally Advanced or Metastatic Urothelial Cancer: A Medicare Perspective

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BACKGROUND: Avelumab, a fully human monoclonal antibody directed against the PD-L1 molecule, was recently approved for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC) who have had disease progression during or following platinum-containing chemotherapy.

OBJECTIVE: To estimate the budget impact of adding avelumab as a second-line (2L) treatment option for locally advanced or mUC from a Medicare perspective.

METHODS: An economic model was developed to estimate the budget impact of adding avelumab to a U.S. health plan over 5 years from a Medicare perspective. Treatments in current market mix (i.e., market without avelumab) included immunotherapies (atezolizumab, nivolumab, pembrolizumab) and chemotherapies. In the revised market mix (i.e., market with avelumab), avelumab was assumed to displace shares of immunotherapies proportionally, with uptake in 2L mUC patients of 0.7% in year 1, 5.9% in year 2, 4.8% in year 3, and 3.8% in year 4 and 5. Number of eligible patients, treatment duration (for estimating treatment, administration, and adverse event [AE] costs), and progression-free and overall survival inputs were extracted from published epidemiological data and clinical trials. Risks of AEs were obtained from FDA labels and published literature. Drug costs were based on average sales price (ASP) or average wholesale price +6% where ASP was not available. Cost inputs (2017 values) were taken from standard U.S. sources. Sensitivity analyses were performed including variations in disease management and AE costs, number of eligible patients, treatment duration, and market shares.

RESULTS: For every 1,000,000 Medicare beneficiaries, a total of 269 patients over 5 years were estimated to be eligible for avelumab. The introduction of avelumab was estimated to have an increase in per member per month (PMPM) cost of $0.0008 in budget year 1, $0.0067 in year 2, $0.0054 in year 3, and $0.0042 in year 4 and 5. Total costs per eligible patient were estimated to be $15,650 and $15,730 per month, prior to and after the introduction of avelumab, respectively, with 2L drug costs representing 12% of the total cost. The marginal increase in the budget was mainly attributed to longer survival with avelumab. The budget impact ranged from 0.50% to 3.77% across various scenarios with incremental PMPM cost in budget year 5 ranging from $0.0008 to $0.0250.

CONCLUSIONS: This budget impact analysis suggests that the adoption of avelumab will have a modest budget impact on a typical Medicare health plan.

SPONSORSHIP: Merck KGaA and Pfizer.

C16 Budget Impact of Introducing Avelumab as a Second-Line Treatment for Locally Advanced or Metastatic Urothelial Cancer in the United States

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BACKGROUND: Avelumab, a fully human monoclonal antibody directed against the PD-L1 molecule, was recently approved in the U.S. for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC) who have had disease progression during or following platinum-containing chemotherapy.

OBJECTIVE: To estimate the budget impact of adding avelumab as a second-line (2L) treatment option for locally advanced or mUC to a commercial health plan in the United States (U.S.).

METHODS: An economic model was developed to estimate budget impact of adding avelumab to a commercial health plan of 2,500,000 members over 5 years. Treatments in current market mix (i.e., without avelumab) included immunotherapies (atezolizumab, nivolumab, pembrolizumab) and chemotherapies. In the revised market mix (i.e., with avelumab), avelumab was assumed to displace shares of immunotherapies proportionally, with uptake in 2L mUC patients of 0.7% in year 1, 5.9% in year 2, 4.8% in year 3, and 3.8% in year 4 and 5. Number of eligible patients, treatment duration (for estimating treatment, administration, and adverse event [AE] costs), progression-free and overall survival inputs were extracted from published epidemiological data and clinical trials. Risks of AEs were obtained from FDA labels and published literature. Drug costs (average wholesale price) were taken from the Redbook 2017, cost inputs (2017$US) were from standard U.S. sources. Various scenario analyses were performed including varying the drug, disease management, and AE costs, number of eligible patients, treatment duration, and market shares.

RESULTS: Over 5 years, a total of 154 commercially insured patients was estimated to be eligible to receive avelumab. The introduction of avelumab was estimated to have a marginal impact to the budget, with an increase in cost per member per month (PMPM) of $0.0002 in budget year 1, $0.0015 in year 2, $0.0012 in year 3, and $0.0010 in year 4 and 5. Total cost per eligible patient was $17,600 and $17,678 per month, prior to and after the introduction of avelumab, respectively, with costs of 2L treatments represented 11% of the total cost. The marginal increase in the budget was mainly attributed to longer survival with avelumab. The budget impact varied by 0.41% to 3.11% across various scenarios with incremental PMPM in budget year 5 ranging from $0.0001 to $0.0071.

CONCLUSIONS: The introduction of avelumab was estimated to lead to a marginal budget impact on U.S. commercial health plan, while providing an added treatment option for a disease with high unmet need.

SPONSORSHIP: Merck KGaA and Pfizer.

C17 Economic Burden of Relapsed and/or Refractory Acute Myeloid Leukemia in Patients in the United States: A Retrospective Analysis of a U.S. Commercial Payer Database

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BACKGROUND: Acute myeloid leukemia (AML), a clonal disorder of hemopoietin stem cells, is estimated to affect 21,380 new patients during 2017 in the U.S. Detailed real-world cost estimates for relapsed-refractory (R/R) AML patients in the U.S. commercially insured population are scarce.

OBJECTIVE: To examine healthcare resource utilization and direct healthcare costs in U.S. R/R AML patients.

METHODS: U.S. claims data from PharMetrics Plus were linked to a charge master hospital database to identify incident adult patients with ≥2 outpatient or ≥1 inpatient claims with an AML diagnosis from 1/1/2008 to 3/31/2016. To assure adequate cost capture, patients were required to have continuous health plan enrolment for ≥6 months pre and ≥3 months post the first diagnosis date, and followed post active treatment (high/low intensity chemotherapy or transplant). Patients were considered R/R if they had: (1) an AML relapse ICD-9 diagnosis code (205.02; R/R code), or (2) a new line of therapy (LOT; new agent or after 90-day gap) post initial active treatment (LOT R/R). Data accrual began 2 weeks prior to R/R event and ended at last follow-up; all-cause healthcare resource utilization and costs were evaluated during this period. Cost and follow up period were reported as mean (SD).

RESULTS: Of 2,170 identified AML patients receiving high or low intensity chemotherapy, the R/R sample consisted of 119 R/R code (mean age 56.3 years) and 791 LOT R/R patients (mean age 51.7 years). R/R code patients had a mean (SD) follow-up of 7.6 (9.5) months and a total costs of $145,634 ($213,724); hospitalization occurred in 74.8% of patients at a cost of $101,420 ($185,548); physician's office visits in 89.9% of patients at costs of $3,340 ($3,872) and outpatient pharmacy in 79.0% of patients at $6,108 ($11,348); 38.7% of patients had at least one emergency room (ER) visit that did not lead to hospital admission at a cost of $683 ($1,900). LOT R/R patients had a follow-up of 13.3 (14.8) months and higher total costs of $406,337 ($386,971); hospitalization (94.8% of patients) was the most costly component $274,472 ($294,500), while costs were $9,686 ($11,902) for physician's office visits (99.2% of patients) and $19,217 ($40,725) for outpatient pharmacy (92.3% of patients); 52.1% had ER visit at a cost of $1,887 ($13,507).

CONCLUSIONS: This resource utilization and cost analysis establishes a substantial burden in patients with R/R AML following initial treatment, with hospitalization being a frequent occurrence, and the major cost driver.

SPONSORSHIP: Astellas Pharma.

C18 Cost Savings Opportunity from Utilizing Less Costly Granulocyte Colony-Stimulating Factors Via Step Therapy

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BACKGROUND: Granulocyte colony-stimulating factors (G-CSF) is one of the most costly oncology support categories to manage. In 2015, G-CSF spend was $1.99 and $4.32 PMPM for commercial and Medicare lines of business, respectively. This cost is largely driven by Neulasta and Neupogen. Zarxio is the first FDA-approved biosimilar to Neupogen. Granix is also highly similar to Neupogen, but because it was approved prior to the establishment of the 351(k) pathway, it is not considered a biosimilar. ASCO Guidelines on the "Use of WBC Growth Factors" suggest that choice of G-CSF agent should be based on convenience, cost, and clinical situation. Clinical similarities and guideline support provide basis for product preferencing in this category for less costly alternatives.

OBJECTIVE: To demonstrate utilization trends and savings potentials through implementation of step therapy (ST) in the G-CSF category.

METHODS: A ST was implemented on October 1, 2016 that required use of Zarxio or Granix prior to Neupogen for commercial members in a regional health plan covering 2.7 million lives. Prior Authorization (PA) request information and medical claims data from January 1, 2016 to December 31, 2016 for Granix, Neulasta, Neupogen, and Zarxio were analyzed to determine the impact of this ST. Statistical significance was calculated via two-sample equal variance test ($\alpha = 0.05$).

RESULTS: 5,755 PA requests were approved for 3,010 unique members between January 1, 2016 and December 31, 2016. Compared to the average for Q1 to Q3 2016, the number of unique utilizers for Granix and Zarxio increased from 121 to 191 (58%; $P = 0.008$) in Q4 2016, while Neupogen decreased from 192 to 54 (255%; $P = 0.03$). Utilizers of Neulasta remained stable. Medical claims analysis reflected similar trends. Among short acting G-CSF products, absolute change in market share for Granix, Zarxio, and Neupogen was +12% and +18%, and -30% respectively. Market share for Neulasta was not impacted. Given a difference in wholesale acquisition cost (WAC) between Zarxio and Granix compared to Neupogen, $106,980 in savings was achieved in Q4 2016, 10% of total short acting G-CSF spend. Projected total cost avoided by the end of 2017 is $662,278. These savings estimates do not include potential manufacturer rebates.

CONCLUSIONS: ST through Granix or Zarxio prior to Neupogen is a clinically appropriate way to generate savings. With additional market competitions, opportunities such as this may help fight against the ever-rising cost of healthcare and provide patients with more cost-effective options without compromising quality of care.

SPONSORSHIP: Magellan Rx Management.

C19 Real-World Use of Supportive Care During Front-Line Chemotherapy in Patients with Hodgkin's Lymphoma in the United States

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BACKGROUND: Hodgkin lymphoma (HL) is a hematologic malignancy for which outcomes may be determined by utilization of supportive care; however, there is minimal evidence regarding the real-world utilization of supportive care during frontline (FL) therapy.

OBJECTIVE: To demonstrate current real-world utilization of supportive and ancillary care in a large insured U.S. population of HL patients during FL therapy.

METHODS: This retrospective analysis used the MarketScan Commercial and Medicare Supplemental administrative claims databases to select adults (age > 18 years) with ≥ 1 inpatient or 2 outpatient claims with an HL diagnosis (ICD-9 201.xx and excluding 201.0x [Hodgkin's paragranuloma], 201.2x [Hodgkin's sarcoma] and 201.4x [lymphocytic-histiocytic predominance]) from 1/1/2010 to 9/30/2015. Eligible patients were required to have continuous health plan

enrollment for >6 months prior to the HL diagnosis, no other primary cancer prior to the HL diagnosis, and initiate treatment with a multi-agent FL regimen indicative of curative intent. Supportive care utilization was measured during the 6 months prior to the index date (date of FL failure or randomly assigned for patients without a failure event). FL failure was defined as the earliest of restarting HL treatment or initiating radiation therapy after discontinuation (gap >60 days with no FL treatment), a switch to a new HL treatment, or a hematopoietic cell transplant procedure.

RESULTS: A total of 795 HL patients met the study criteria, with mean (SD) age 38.5 (15.3) years, 47.5% were female. The mean (SD) baseline Deyo-Charlson Comorbidity Index score was 2.9 (1.9). The average duration of FL therapy was 126 (SD 55.7) days and the majority (77.6%) received doxorubicin, bleomycin, vinblastine, dacarbazine (ABVD) combination regimen. 14% of HL patients received radiation during their FL regimen. Most HL patients utilized supportive care during FL, and the most common therapies included anti-emetics (94.2%), steroids (85.2%), antibiotics (69.3%), granulocyte-colony stimulating factors (G-CSF; 49.6%), and anti-virals (19.1%) respectively. Of the patients with G-CSF utilization (N=394) 39.8% were treated with filgrastim and 73.9% were treated with pegfilgrastim.

CONCLUSIONS: Supportive and ancillary care are needed for most HL patients treated with FL therapy. Further research is required to determine optimal supportive care utilization that could enhance the disease management and treatment effectiveness clinically and economically.

SPONSORSHIP: Seattle Genetics.

C20 Risk of Neutropenic Hospitalization in Non-Hodgkin's Lymphoma Cancer Patients Receiving Chemotherapy

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BACKGROUND: Prophylaxis use of granulocyte colony-stimulating growth factor (GCSF) is recommended for chemotherapy regimens with high risk for neutropenic hospitalizations, while the clinical benefit of GCSF prophylaxis is less clear for low-to-intermediate risk regimens. This lack of clarity leads to variation in GCSF use across regimens of comparable risk for inducing neutropenic hospitalizations among patients with Non-Hodgkin's Lymphoma (NHL).

OBJECTIVE: To describe GCSF prophylaxis use and subsequent outcomes in patients with NHL receiving chemotherapy regimens.

METHODS: NHL patients ≥18 years were identified from a medical and pharmacy claims database for 14 commercial U.S. health plans. All patients received first-cycle chemotherapy for NHL cancer during 2008-2013. Primary prophylaxis (PP) was defined as GCSF administration within 5 days from start of chemotherapy. Outcome was neutropenia, fever, or infection-related hospitalization within 21 days from start of chemotherapy. Multivariable regressions and absolute risk difference (ARD) were used.

RESULTS: A total of 6,860 NHL patients received chemotherapy, among which 2,583 (37.7%) received PP. Patients with and without PP had similar characteristics with median age of 62 and 46% with at least 1 non-cancer comorbidity. The two most commonly used chemotherapy regimens were combination of cyclophosphamide, rituximab, doxorubicin and vincristine (R-CHOP, n=2,398, 66.6% PP), and rituximab alone (n=1,758, 6.4% PP). Risk for neutropenic hospitalization between patients with and without PP was the same for all chemotherapies (6.1% PP; 6.1% no PP; adjusted odds ratio [AOR] 0.86; 95% CI: 0.67, 1.07), and for rituximab alone (2.7% PP; 3.3% no PP; AOR 0.37; 95% CI: 0.10, 1.30), but PP was associated with reduced risk for the R-CHOP regimen (5.8% PP; 8.0% no PP; AOR 0.64; 95% CI: 0.46, 0.90). Comparing to patients receiving the R-CHOP regimen without PP, 2 additional patients per 1000 treated would benefit from PP (ARD -0.2%, 95% CI: [-4.5%, -0.1%]). Similar risk was observed between PP and non-PP for the 3rd and 4th most commonly used chemotherapy regiments (n=573, 539 each).

CONCLUSIONS: For NHL cancer patients on chemotherapy, primary GCSF prophylaxis showed some benefit in lowering neutropenic hospitalization in those receiving the R-CHOP regimen, while not for other common regimens. Further evaluation is needed to better understand which patients benefit most from GCSF prophylaxis in this setting.

SPONSORSHIP: Anthem.

D2 U.S. Medical and Pharmacy Director Cancer Concerns in 2017

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BACKGROUND: Cancer is costly, managed by a variety of treatments that include traditional and robotic surgery, radiation, chemotherapy, and immunotherapy. Pharmaceutical treatments are shifting from chemotherapy with limited effectiveness and multiple side-effects to effective targeted immunotherapies with fewer side-effects, multiple treatment pathways with indications alone and in combination, and receiving fast-track approvals.

OBJECTIVE: To determine the cancers most concerning to managed care plans, a survey invitation was sent to medical and pharmacy directors (MDs+PDs) of U.S. health plans, insurers, and PBMs.

METHODS: Managed care (MC) MDs+PDs completed an online interactive survey. Topics included: advisor+plan information; Ranking (highest=1 to 13=lowest) of cancer-types; Copays, benefit-design, cancer management, top concerns today and in 5 years from budgetary and medical points of view.

RESULTS: The survey was completed by 52 MDs+PDs (11.3%): 55.8% were MDs and 57.7% worked for health plans/IDNs/PPOs/IPAs; 9.6% for PBMs; 3.8% for Government. Plans were National=41.9%; Regional=34.9%; or Local=23.3%. Advisors/Plans could cover multiple types of members: commercial (54.2%=FFS; 70.8%=HMO/PPO), Medicaid (Traditional=22.9%; HMO/PPO=62.5%); Medicare (66.7%; Traditional=22.9%; PDP only=45.8%) and Employer/Self-funded lives=66.7%. Oncology was tied for the top ranked Specialty Pharmacy condition covered 84.4% (vs. 64.3% last year) and 34.1% of advisors reported they participated in Oncology accountable care/disease management organizations. Based on average rankings (out of 13) the most concerning cancers were: Lung=2.54; Breast=2.72; Colon+Rectal=3.64; Prostate=6.0; Myeloma=6.44; Leukemia= 6.97; Melanoma=7.08; Pancreatic=7.72; Non-Hodgkins Lymphoma=7.82; Kidney=8.85; Endometrial=9.76; Bladder=9.97; and Thyroid=11.38. When asked about cancer management 48.7% of the plans/advisors sometimes leave oncology specialists alone; 65.0% of plans/advisors always follow NCCN guidelines; 56.4% sometimes follow other guidelines or pathways; and 38.5% sometimes follow internal protocols. Cancer/oncology was consistently reported the top concern from medical care (50% today, 42.5% in 5 years) and budgetary (35.7% today, 57.5% in 5 years) points of view.

CONCLUSIONS: The environment for cancer treatment is undergoing a series of changes. The shift from traditional chemotherapies toward targeted immunotherapies and the potential cost implications requires

payor medical and pharmacy directors to focus on, adapt and evaluate these newer agents and pathways rapidly as they become available.

SPONSORSHIP: TPG-National Payor Roundtable.

D3 Retrospective Claims Data Comparison of Febrile Neutropenia Incidence Between Biosimilar Filgrastim-sndz/EP2006 and Reference Filgrastim in Patients Treated with Chemotherapy Regimens for Nonmyeloid Cancers

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BACKGROUND: Granulocyte colony-stimulating factors (G-CSFs) are utilized to decrease the incidence of febrile neutropenia (FN) in patients with nonmyeloid cancers undergoing chemotherapy (CT) treatments.

OBJECTIVE: This retrospective study evaluates the proportion of patients with FN in cycle 1 of CT treatment between biosimilar filgrastim-sndz/EP2006 and reference filgrastim.

METHODS: Non-myeloid cancer patients enrolled in commercial and Medicare advantage plans between March 2015 and June 2016 (Optum Research Database) and received filgrastim-sndz or reference filgrastim during completed cycle 1 of CT were included in the study. Patients receiving hematopoietic stem cell transplants, pregnant patients, and patients with missing data were excluded. Proportion of patients with FN in CT cycle 1 was evaluated between the two cohorts using equivalence testing after adjusting for differences in baseline demographic and clinical characteristics by the inverse probability of treatment weighting of propensity scores method. 90% confidence intervals were calculated using the bootstrap method. FN was identified using ICD-9 codes for neutropenia (N), fever (F), and bacterial and fungal infections (I). The incidence of FN between the two cohorts was considered equivalent if the confidence intervals were within ± 6.0%.

RESULTS: Mean age of the study cohort (n = 3,459; 162 filgrastim-sndz and 3,297 reference filgrastim patients) was 64.5 years (SD: 12.9 years) and 63.3% were female. G-CSF was initiated within 5 days of CT initiation (prophylaxis for FN) in 1,682 (48.6 %) of the study patients. Average length of CT cycle [21.7 (filgrastim-sndz) vs. 22.2 days (reference filgrastim); $P = 0.424$] and baseline Charlson Comorbidity Index score [5.65 (filgrastim-sndz) vs. 5.75 (reference filgrastim); $P = 0.604$] was similar between the 2 cohorts. Weighted adjusted results were equivalent between the 2 cohorts, respectively: N and F: 1.38% (filgrastim-sndz) vs. 0.92% (reference filgrastim); difference: 0.47 (90% CI: -0.86-2.87); N and I (bacterial or fungal): 2.30% (filgrastim-sndz) versus 1.73% (reference filgrastim); difference: 0.57 (90% CI: -1.57-4.41); N, I, and F: 0% (filgrastim-sndz) vs. 0.30% (reference filgrastim); difference: -0.30 (90% CI: not able to calculate due to zero events).

CONCLUSIONS: This retrospective claims data study demonstrated statistical equivalence in the proportion of patients with FN (based on different definitions of FN) in CT cycle 1 treatment between biosimilar filgrastim-sndz/EP2006 and reference filgrastim in patients with nonmyeloid cancers.

SPONSORSHIP: Sandoz.

D5 Clinical Pathways for Myeloid Growth Factors Leads to Appropriate Use in Oncology Treatment

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BACKGROUND: Myelosuppressive cancer chemotherapy leads to major toxicities including febrile neutropenia and infection. In the curative setting, prophylactic use of myeloid growth factors (MGF) is recommended when the risk of febrile neutropenia is greater than 20% and no other equally effective and safe regimen is available. In the palliative setting, MGF use can be avoided by dose reduction or delay. MGFs should also not be routinely used for patients with neutropenia without fever. New Century Health is committed to helping oncology practices deliver high quality care to patients and providers.

OBJECTIVE: Based on the 2015 updates to the American of Clinical Oncology (ASCO) guidelines, NCH created a Clinical Pathway with oncologist consultative support for MGF that would help increase the quality of care.

METHODS: Consultative requests received one year prior to the intervention period (baseline period: April 2015 to March 2016) were compared to requests received throughout the implementation of the project in the Medicare population (intervention period: April 2016 to March 2017). Two primary outcomes were evaluated: the number of withdraws/recommended adverse determinations (RADs) and potential cost-savings. Descriptive statistics were conducted to describe patterns in community practice and estimated costs. Chi-square ($\chi 2$) tests were performed to evaluate differences in requests during the baseline period as compared to the intervention period. Wilcoxon signed-rank (z) tests were performed to evaluate difference in potential cost savings in the intervention period due to clinical interventions.

RESULTS: The findings suggest that there was a significant difference in community practice in the intervention period as compared to the baseline period in Florida ($\chi 2 = 17.92$, $P = 0.001$) and Arizona ($\chi 2 = 45.49$, $P = 0.001$); with a greater percent of withdrawn/RADS in the intervention period (Florida: 7.5% vs. 20.2%; Arizona: 12.7% vs. 30.2%). The results suggested there was a significant increase in potential cost savings in the intervention period in Florida ($z = -5.26$, $P = 0.001$) and Arizona ($z = -7.32$, $P = 0.001$) due to the clinical interventions. Sensitivity analyses were also conducted and indicated further support for these findings.

CONCLUSIONS: The implementation of a clinical pathway, with consultative support, aided in proper usage of MGFs through provider education and resulted in potential cost-savings. This analysis further supports the benefit of pathway integrated guidelines applied in community practice settings.

SPONSORSHIP: None.

D6 Declines in Health-Related Quality of Life Are Associated with Increased Rates of Healthcare Resource Utilization in Patients with Light Chain Amyloidosis

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BACKGROUND: Light chain (AL) amyloidosis is a rare, complex disease that impacts humanistic burden and healthcare resource utilization (HCRU).

OBJECTIVE: To examine whether changes in health-related quality of life (HRQoL) are associated with HCRU, specifically rates of emergency room (ER) visits and hospitalizations.

METHODS: The analysis sample included patients with AL amyloidosis (n = 153) who completed four online surveys (an initial survey and 6-, 12-, and 18-month follow-up surveys) in a non-interventional, longitudinal online study. HRQoL was measured at each time point using the SF-36v2 Health Survey (SF-36v2). The SF-36v2 measures

eight domain scales (physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional health problems (RE), and mental health (MH)) and two component summary measures: physical (PCS) and mental (MCS). Change scores for each SF-36v2 domain and summary measure were defined as the difference between initial and six-month observations. Negative change scores indicate declines in functioning and well-being. HCRU outcomes were defined as the cumulative counts of self-reported ER visits and hospitalizations for the 12-month period between 6- and 18- month follow-ups. Each HCRU outcome was regressed on change scores using separate negative binomial models for each SF-36v2 domain or summary component. Models also included the initial SF-36v2 score as an independent variable. Incident rate ratios (IRR) were interpreted in terms of the point decline that corresponded to the minimally important changes (MIC) for each SF-36v2 score.

RESULTS: RP, BP, and PCS were associated with greater rates of both ER visits and hospitalizations. In particular, declines in PCS equivalent to an MIC (3.4 points) were associated with a 42% greater rate of ER visits and a 35% greater rate of hospitalizations. Declines in GH were associated with a greater rate of ER visits. Aspects of HRQoL related to mental well-being (VT, SF, RE, MH, or MCS) were not associated with either HCRU outcome.

CONCLUSIONS: Declines in HRQoL, specifically in areas related to physical well-being, were associated with greater rates of ER visits and hospitalizations in patients with AL amyloidosis. By regularly assessing HRQoL, AL amyloidosis specialists may be able to identify patients who are in need of increased levels of care and at risk for more monitoring and expensive resource utilization.

SPONSORSHIP: Prothena Biosciences.

D7 U.S. Budget Impact Analysis for Daratumumab in Combination with Lenalidomide and Dexamethasone, Bortezomib and Dexamethasone, or Pomalidomide and Dexamethasone for the Treatment of Patients with Relapsed/Refractory Multiple Myeloma

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BACKGROUND: Daratumumab (DARA), in combination with lenalidomide (LEN) and dexamethasone (DEX), bortezomib (BOR) and DEX, or pomalidomide (POM) and DEX is FDA approved for the treatment of patients with relapsed/refractory multiple myeloma (MM).

OBJECTIVE: To estimate the 1-year budget impact of adding daratumumab combination regimens to U.S. Commercial and Medicare health plans.

METHODS: The number of treatment eligible patients in a hypothetical U.S. Commercial or Medicare health plan were estimated using MM prevalence data (U.S. SEER statistics) and published estimates of the number of patients transitioning between lines of therapy. Medicare eligible patients in the Commercial plan were removed from the commercial analysis. Other FDA-approved, NCCN-recommended second-line therapies with ≥5% use (by U.S. Claims data) were included. These alternative therapies were: DARA monotherapy, POM/DEX, carfilzomib/DEX, LEN/DEX, carfilzomib/LEN/DEX, BOR/LEN/DEX and ixazomib/LEN/DEX. Daratumumab combinations were assumed to decrease the market share of all alternative therapies but primarily impact DARA monotherapy and other triplets. Drug administration and dosing, treatment duration (estimated from progression-free survival [PFS]), required comedications, post-progression therapy, monitoring requirements and adverse event (AE) rates were based upon FDA prescribing information or clinical trials. AEs ≥ grade 3, occurring in ≥5% of patients were included. Red Book wholesale acquisition costs were used as drug acquisition costs. Costs of drug administration, AE management, and patient monitoring were based on the Centre for Medicare and Medicaid Services payment rates or published literature.

RESULTS: Over a 1-year time horizon, hypothetical 1,000,000-member U.S. Commercial and Medicare health plans were estimated to have 141 and 826 eligible patients, respectively. The budget impact of adding DARA combination regimens to these plans was $960,673 ($0.08 per-member-per-month [PMPM]) and $5,617,689 ($0.47 PMPM), respectively. The per-treated-member-per-month [PTMPM] cost to either plan was $567.09. Sensitivity analyses indicated that treatment duration and treatment cost were important cost drivers.

CONCLUSIONS: Addition of DARA combinations to U.S. Commercial or Medicare plans may result in a budget impact due in part to longer treatment duration with DARA combinations compared with the alternative therapies. As is common with modelling, some assumptions were necessary. Results may not be generalizable to all plans.

SPONSORSHIP: Janssen Scientific Affairs.

D8 Resource Utilization Associated with Cytomegalovirus in Hematopoietic Stem Cell Transplant Recipients: A Commercial Payer Perspective

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BACKGROUND: Recipients of hematopoietic stem cell transplant (HSCT) are at high risk for complications following transplant, including graft failure, graft versus host disease (GvHD), and infections, including cytomegalovirus (CMV).

OBJECTIVE: This research aims to describe the rate and cost of complications in the year following HSCT with a focus on CMV and other infectious complications.

METHODS: Participants in the Truven Health MarketScan Research Database who had an ICD-9-CM procedure code for allogeneic HSCT (index event) between 2010 and 2015, were 18 years or older and had 12 months of continuous enrollment pre- and post-index hospitalization were included in the study. Patients who died within 12 months post-index were also retained in the sample. Total healthcare costs were calculated during the first year post HSCT and stratified by the presence of CMV during follow-up.

RESULTS: There were 1,825 participants included in the cohort (mean age 50.8 years [SD = 12.8]; 42.5% female) and 91.6% were under age 65 at the time of the HSCT. Approximately one quarter of patients (22.5%) had CMV infection or disease during follow-up. Other common complications in the first year post-transplant were bacterial infections (49.0%), fungal infections (26.0%), neutropenia (48.8%), acute GvHD (28.0%), and chronic GvHD (25.4%). Mortality within one year post-HSCT was also common (24.1%). Mean overall healthcare costs were $510,791 [SD = $459,733], inclusive of the index HSCT. Participants with a CMV event had significantly higher mean inpatient costs ($677,240 vs. $462,562), outpatient costs ($141,396 vs. $94,312) and prescription drug costs ($27,391 vs. $22,082) compared to participants without a CMV infection (all $P < 0.001$). Patients with CMV were more likely have an inpatient readmission within 60 (31.2% vs. 19.4%), 100 (50.0% vs. 30.5%) or 365 days (78.0% vs. 57.8%, all $P < 0.001$). Patients with CMV also had a higher rate of inpatient stays than those without CMV during the one year follow-up period (mean 3.3 vs. 2.3 admissions, $P < 0.001$).

CONCLUSIONS: CMV represents a substantial economic burden to payers and hospitals following an HSCT procedure. Future strategies that minimize the risk of CMV infection and/or disease may result in significant economic benefit.

SPONSORSHIP: Merck & Co.

D9 Cost Savings Associated with Subcutaneous C1-Inhibitor (Human) Long-Term Prophylaxis for Hereditary Angioedema

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BACKGROUND: C1-esterase inhibitor (human) subcutaneous (C1-INH(SC)) is a new treatment for long-term prophylaxis (LTP) for hereditary angioedema (HAE). HAE disease burden is high, and includes unpredictable, painful and temporarily disfiguring attacks of swelling that can lead to hospitalization and possible death.

OBJECTIVE: An economic model was constructed to estimate breakthrough attacks avoided, acute medication cost savings by reduction in breakthrough attacks, and overall cost savings associated with LTP with C1-INH (SC; 60 IU/kg) compared with C1-esterase inhibitor (human) given intravenously (C1-INH [IV]) in patients with ≥2 attacks/month.

METHODS: A decision tree model was used to estimate the annual number of HAE attacks and attack-related annual costs for a typical HAE patient from a United States third-party payer perspective. Branches included attack severity, on-demand treatment including administration location, emergency department (ED) visits and hospitalizations. The median reduction in attacks and other inputs for C1-INH (SC) were from its clinical trial. C1-INH (IV) efficacy and other parameters were from published literature. Drug cost and administration, monitoring, ED, hospitalization, and port access costs were considered.

RESULTS: Per HAE patient over 1 year, approximately 50 attacks were projected for on-demand therapy only. LTP reduced attacks dramatically with 2.3 attacks projected with C1-INH (SC; median reduction of 95%) and 22.2 with C1-INH (IV; median reduction of 53%). The cost savings between C1-INH (SC) and C1-INH (IV) was $267,128 (LTP drug cost: $85,028, acute on demand drug: $157,968 and other medical cost: $11,274). Overall, the base-case incremental cost-effectiveness per attack avoided for all comparisons between C1-INH (SC) and C1-INH (IV) was cost saving (lower costs, greater effectiveness) from a payer perspective. Based on the findings of a probabilistic sensitivity analysis , 100% of the iterations fell below a $50,000 willingness to pay threshold.

CONCLUSIONS: LTP treatment with C1-INH (SC) may result in reduced frequency of attacks and overall cost savings due to cost of drug (LTP and on demand) acquisition, administration and other medical costs compared with C1-INH (IV).

SPONSORSHIP: CSL Behring.

D10 Healthcare Resource Utilization and Costs of Care Among Patients with Acute Graft-Versus-Host Disease Post-Allogeneic Hematopoietic Stem Cell Transplant in a Large Managed Care Plan

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BACKGROUND: Acute graft-versus-host disease (aGVHD) is a common complication of allogeneic hematopoietic stem cell transplant (allo-HSCT), usually occurring within 100 days of HSCT. aGVHD increases morbidity and mortality post HSCT.

OBJECTIVE: This analysis describes healthcare resource utilization and costs of care associated with aGVHD post-HSCT.

METHODS: Administrative claims data from the Optum Research Database was used to identify patients who received allo-HSCT from 01/01/10 through 08/31/16. The date of the first HSCT claim was defined as index date. Patients included in the analysis were ≥12 years of age, and enrolled in a commercial or Medicare Advantage plan ≥6 months before and ≥4 months (120 days) after index (death ≤4 months post-index allowed). Patients with aGVHD were defined by ≥2 outpatient claims or ≥1 inpatient or emergency room (ER) claim for the following: (1) aGVHD (ICD code 279.51 or D89.810) at any time between HSCT date and the end of follow-up, or the day before chronic GVHD diagnosis, whichever occurred first; or (2) unspecified GVHD (ICD code 279.50 or D89.813) within 100 days of HSCT or the day before chronic GVHD diagnosis, whichever occurred first. Patients in comparison group had no claims for GVHD post-index that met the criteria for patients with aGVHD. All-cause healthcare utilization and costs during 100 days and 12 months post-index were described for patients with aGVHD vs. comparison. Chi-square test and unpaired t-test were used to compare categorical variables and continuous variables, respectively.

RESULTS: 723 patients with aGVHD and 456 patients in comparison group were included in the analysis. Patients with aGVHD were similar in mean age (50 years), gender (female 41%), and insurance (commercial 88% and Medicare 12%) to comparison patients. Patients with aGVHD had more office visits, outpatient consultations, ER visits, and inpatient admissions during 100-day and 12-month post HSCT (all $P<0.001$). Mean 100-day and 12-month total costs were higher for patients with aGVHD vs. comparison ($316,458 vs. $222,671, difference in mean $93,787; $466,720 vs. $277,632, difference in mean $189,087; both $P<0.001$, respectively).

CONCLUSIONS: Acute GVHD is associated with higher healthcare resource utilization and costs of care after allo-HSCT. The difference in healthcare resource utilization and costs was observed within 100 days of transplant, and doubled over the year post HSCT.

SPONSORSHIP: Incyte.

E00-E90 Endocrine, Nutritional, and Metabolic Diseases *(e.g., Growth Hormone, Diabetes, Lipids)*

E2 How Can We Use Budget Impact Models to Explore Cost Drivers and Heterogeneity Within Our Plan Population?

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BACKGROUND: Traditional budget impact models estimate the financial consequences of a new drug entering the market. However, payers may build their own models to estimate the impact of formulary or policy changes. Taken one step further, payer-built budget impact models may be used to explore cost drivers and heterogeneity within a plan population. Understanding cost drivers and heterogeneity within a plan population are important for payers to be able to strategically manage their populations. For example, high utilization and spending in particular subgroups often needs utilization management programs targeting those subgroups. Likewise, understanding the cost drivers of a formulary or policy change will help payers understand what

areas to monitor closely during implementation of the formulary or policy change. The example provided in this poster is from a budget impact model that was created to assess formulary changes made by TRICARE in February 2016.

OBJECTIVE: To predict cost drivers of the budget impact of antidiabetic formulary changes.

METHODS: A budget impact model was created in Microsoft Excel using historical utilization data from the payer. This model was described in a poster presentation at the 2017 AMCP Annual Meeting. Cost drivers were determined in two ways: (1) sensitivity analyses addressing various types of parameter and structural uncertainty; varying market share shifts; comparing the budget impact for different cost categories such as antidiabetic drug classes of interest, drug treatment of side effects, antidiabetic supplies, and medical services, and (2) subgroup analyses examining heterogeneity and comparing the budget impact for various pharmacy points of service, plan types, and states.

RESULTS: The model predicted a one-year savings of approximately $31 million due to the formulary changes. Of the $31 million savings, $18 million came from savings at the retail network point of service. At year 1, the model was most sensitive to worst and best case scenarios where all shifts in market share were 0% or 100%. Shifts in market share for the glucagon-like peptide-1 receptor agonist (GLP1RA) were most sensitive.

CONCLUSIONS: When implementing formulary changes, the payer should pay special attention to market share shifts for the GLP1RA drug class and retail network pharmacies.

SPONSORSHIP: Agency for Healthcare Research and Quality.

E3 Bridging the Gap Between Self-Reported and Claims-Derived Adherence Measures for Basal Insulin Among Patients with T2DM

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BACKGROUND: Claims-based adherence measures (CBAMs) are widely used to measure adherence for injectables such as basal insulin (BI). However, CBAMs may not be accurate in measuring adherence for individualized regimens of BI. No studies have examined the relationship between survey-based adherence measures (SBAMs) and CBAMs for BI among patients with type 2 diabetes (T2D).

OBJECTIVE: To compare SBAMs and CBAMs for BI among patients with T2D.

METHODS: Adult currently-active, commercially insured survey-eligible patients with ≥1 medical claim for T2DM and ≥3 BI claims were identified during 4/1/15-5/31/16 from claims in the HealthCore Integrated Research Database. Consenting patients completed a survey between 10/1/16-12/31/16 that included BI use questions (current BI daily dose, typical BI refill duration and number of BI fills over past 12-months). Survey data were linked with prior 12-month claims data of participants. Study period was defined as days between the first BI fill to survey date. Medication Possession Ratio (MPR) was calculated 4 ways: (1) SB-MPR: survey-based total BI days supply divided by 365; (2) traditional CB-MPR: total BI days supply from claims divided by treated period; (3) adjusted CB-MPR: traditional MPR multiplied by a ratio of mean interval days between fills to mean drug supply days; and (4) hybrid MPR: expected days of insulin supply (total units of BI dispensed from claims divided by SB dose) divided by study period.

RESULTS: Of 400 survey respondents, 296 initiated insulin ≥12 months prior to survey date and had non-missing values for all claims and survey variables used in the analysis. Median SB BI days supply per fill was 30 days (interquartile range, IQR: 23) and CB BI days supply per fill of 28 days (IQR: 13). Median SB dose was 50 units (IQR: 42) while the CB dose was 60 units (IQR: 50). Hybrid [282 (IQR: 171)] and SB [360 (IQR: 120)] median BI days supply were higher than CB days supply [259 (IQR: 106)]. Median SB MPR score [0.99 (IQR: 0.33)] was highest, followed by hybrid-MPR [0.87 (IQR: 0.48)], adjusted CB-MPR [0.98 (IQR: 0.34)] and traditional CB-MPR [0.80 (IQR: 0.27)]. Based on MPR cut-off of adherent (>80%), the proportion adherent to BI were 76% using SB-MPR; 71% using adjusted CB-MPR, 56% using Hybrid MPR; and 50% using traditional CB-MPR.

CONCLUSIONS: Individualized regimen and dose adjustment complicate insulin adherence research. Survey based methods tend to show greater adherence in basal insulin patients compared to claims based methods, mainly due to differences in dose measurement.

SPONSORSHIP: Eli Lilly.

E4 Long-Term Real-World Cost Burden of Type 2 Diabetes and Associated Microvascular and Macrovascular Complications

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BACKGROUND: Complications associated with type 2 diabetes mellitus (T2DM) pose a significant cost to patients, employers, and payers, but data on the long-term progression and financial impact in the real-world setting are limited.

OBJECTIVE: To estimate the incremental long-term cost and mortality associated with T2DM and related complications.

METHODS: This retrospective, claims-based cohort study identified newly diagnosed (incident) T2DM patients in 2007 (baseline period back to 1/1/2006) from the HealthCore Integrated Research Database. Incident T2DM patients were 1:1 exact matched on demographics to non-T2DM patients and the cohorts were followed for up to 8 years or death; continuous health plan eligibility was required. The subset of incident T2DM patients with claims for ≥1 T2DM complication (T2DMc) any time during the study period were identified. All-cause mortality, and all-cause and DM and DM complication-related healthcare costs (in 2015 USD), were examined for the incident T2DM patients and non-T2DM matched cohorts for each of the 8 follow-up years.

RESULTS: The study included 13,883 T2DM patients and their matched non-T2DM patients. Among the T2DM patients, 11,792 (85%) had T2DMc between baseline and end of follow-up. Median age was 65 and 68 years for incident T2DM and T2DMc patients, respectively, and overall half were females. T2DM patients had a higher mortality (28% vs. 20%) and shorter time to death (median 667 vs. 876 days) compared to non-T2DM patients. Among T2DMc patients, mean all-cause annual costs were greater compared to non-T2DM patients ($15,287 vs. $7,530 baseline, $31,305 vs. $9,497 in post-index year 1, $15,000-$18,000 vs. $8,000-$10,000 years 2-8, all years $P<0.001$). A similar trend was observed for T2DM and T2DMc-related costs (all $P<0.001$). T2DM and T2DMc-related costs were largest during post-index year 1, and accounted for 76-92% of the overall cost difference between T2DMc patients and their matched controls. Incident T2DM patients not having any DM related complications at any time had significantly lower costs compared to non-T2DM patients (all $P<0.001$) between years 2-8 of follow-up.

CONCLUSIONS: Diabetes complication-related costs drive a substantial proportion of the cost burden for T2DM patients. The cost impact of diabetes complications was highest in the year after diagnosis and persisted for at least seven additional years, while the cost of T2DM patients without complications was lower than that for matched non-T2DM patients. These data highlight potential costs that could be offset by early and effective management of T2DM.

SPONSORSHIP: Novo Nordisk.

E5 Reducing Inpatient Hypoglycemia and Cost Containment Via Institutional Culture Change While Preserving the Use of Older Insulin Preparations

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BACKGROUND: A multidisciplinary committee was formed to review issues surrounding glycemic management in an academic, safety net hospital. One initiative focused on reducing hypoglycemic events through the proper choice of basal insulin without imposing restrictions to older agents. Older insulins have been substituted by some institutions for newer, more expensive agents in hopes of decreasing hypoglycemia risk.

OBJECTIVE: Reduce inpatient hypoglycemia without increasing costs associated with newer basal insulins.

METHODS: A stepwise approach was undertaken to shift prescribing practices within the health system including (1) discussions with internal medicine resident leaders (2) revising inpatient insulin order-sets, including a tiered system to guide providers in choosing the most appropriate basal regimen (NPH, glargine, and premixed insulin) for a specific patient population (e.g., observation status) which also aligned with cost-effectiveness strategies (3) consolidating hypoglycemic protocols and correctional scales and (4) system wide education on proper use of basal/bolus therapy for inpatient glycemic management. Specific phrasing within the orderset guides providers in choosing the most appropriate basal options (e.g., use only for patients ready for discharge or preferred for type 1 diabetes).

RESULTS: Prior to structured implementation to drive culture change, premixed insulin was utilized in 53% of hospitalized patients receiving insulin and they incurred a high hypoglycemia rate by patient-day (26% mild and 3% severe). After implementation, 15% utilized premixed insulin and incurred a lower rate of hypoglycemia by patient-day (3% mild and 0% severe). Alternative basal insulin rates prior to the culture change were 45% and 20% for human insulin and analog insulin, respectively. Post implementation, rates were 64% and 21% respectively. Assuming 10 mL vials used/order, the post implementation costs for premixed insulin were lower than if alternatives were used (Premixed: $1,620.53 vs. Basal/Bolus NPH/Reg: $3,241.06 or Basal/Bolus Analog: $14,772.04).

CONCLUSIONS: Premixed insulin should only be used in appropriate patient populations on the inpatient setting. When structured interventions are implemented, the appropriate use of either Premixed, Basal/Bolus NPH/Reg or Basal/Bolus Analogs is increased. Premixed insulin used in a subset of suitable patients results in a low hypoglycemic event rate. Premixed insulin can be kept on the inpatient formulary as a cost containment strategy, however, with proper training and culture change among providers.

SPONSORSHIP: Parkland Health & Hospital System.

E6 Basal Insulin-Use Behaviors, Attitudes, and Adherence Among Type 2 Diabetes Patients: An Analysis of Patient Survey Data

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BACKGROUND: Measuring and monitoring adherence can help improve patient outcomes. Since basal insulin (BI) therapy follows an individualized regimen, it is difficult to estimate BI adherence from claims data alone.

OBJECTIVE: To better understand the relationship between BI use behaviors, attitudes and adherence through a survey of type 2 diabetes (T2DM) BI users.

METHODS: Adult, currently-active, commercially-insured, survey-eligible patients with >1 medical claim for T2DM and >3 BI claims during 4/1/15-5/31/16 were identified from claims in the HealthCore Integrated Research Database. Contacted, consenting, qualified patients completed a patient survey that was developed from focus group themes and questions in the literature. Survey included questions on BI usage behavior, attitudes and adherence, demographics, and other factors. Adherence to BI was defined as a score of 8 on the validated 8-item Morisky Medication Adherence Scale (MMAS-8). Chi-square tests and t-tests were used to determine difference categorical factors and continuous factors between BI adherence groups, respectively.

RESULTS: Of 400 patients who completed the survey (pen = 306; vial = 94), 47% were male, 75% white non-Hispanic, with mean age 57.2 years (standard deviation, SD = 9.4); 60% reported at least some college, and 47% were employed full/part time. In addition to BI, 72% took oral diabetes agents, and 14% used non-insulin injectables. Mean number of diabetes medications was 2.5 (SD = 1.3). Mean current BI daily dose was 54.4 (SD = 36.1) units for pen; 67.5 (SD = 49.2) units for vial. As for dosing frequency, 59% of pen, and 31% of vial users reported taking one injection a day. Of 400 patients, 395 had valid MMAS-8 scores; 34% were adherent to BI. Compared to non-adherent patients, a higher proportion of adherent patients were obese (34% vs. 24%, $P = 0.03$), on stable BI dose for a year (68% vs. 58%, $P = 0.04$), on BI once daily dose (60% vs. 48%, $P = 0.02$), stated their average refill provides enough insulin to last the month (96% vs. 85%, $P < 0.01$), don't change dose based on how their feeling (85% vs. 65%, $P < 0.01$) or glucose level (52% vs. 41%, $P = 0.04$), and were able to determine their correct dose with minimum difficulty (95% vs. 84%, $P < 0.01$). Adherence to BI did not differ age, mode of administration, or frequency of following doctors' advice.

CONCLUSIONS: Findings show adherence to be a multi-faceted behavior affected by a variety of factors. These findings may help identify behaviors and attitudes that promote adherence to BI therapy for T2DM patients.

SPONSORSHIP: Eli Lilly.

E7 The Direct Cost of Cardiovascular Disease-Related Death in Patients with Type 2 Diabetes Mellitus in a Medicare Population

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BACKGROUND: Patients with type 2 diabetes mellitus (T2DM) are at an increased risk of death from cardiovascular disease (CVD); however, there is a lack of data on healthcare resource utilization (HCRU) and costs preceding CVD-related death in T2DM patients ≥65 years of age.

OBJECTIVE: Determine the incremental HCRU and direct medical costs of CVD-related death among Medicare beneficiaries with T2DM prior to their death.

METHODS: The study employed a retrospective, matched-cohort design using the 5% Medicare claims data. Patients aged ≥65 years with a diagnosis for T2DM from 01/01/2013-07/31/2015 were identified. T2DM patients who died of a CVD-related cause were matched 1:1 to those with no evidence of death, on age ± 2 years, sex, geographic region, plan type, and index year. The index date was defined as the date of death or last medical claim with a diagnosis of T2DM for those who did not die. The 2 years preceding the index date were divided into an outcomes period (0 to 12 months prior to the index date) and baseline period (13 to 24 months prior to the index date). All-cause HCRU and direct costs were assessed during the outcomes period and in quarterly increments and compared between matched cohorts using McNemar's chi-square tests and paired t-tests.

RESULTS: 8,765 patients who died were matched to 8,765 patients who did not die. Average age of patients was 79.9 ± 8.0 years, 51.1% were male for both cohorts. Patients who died had a higher mean Charlson Comorbidity Index score than those who did not die (3.3 ± 2.5 vs. 1.8 ± 1.9; $P<0.001$). A significantly larger proportion of patients who died used inpatient (90.1% vs. 23.6%; $P<0.001$) and emergency department (95.9% vs. 37.6%; $P<0.001$) services compared to patients who did not die during the year prior to death. Medical costs were 5.3 times higher ($57,128 vs. $10,785; $P<0.001$); inpatient costs 8.7 times higher ($P<0.001$) and outpatient costs 2.5 times higher ($P<0.001$) than those of patients who did not die in the year prior to death. Medical costs for patients who died were 2.5, 2.9, 3.6 and 10.9 times higher during the time period 10-12, 7-9, 4-6 and 0-3 months prior to death compared to those who did not die, respectively (all $P<0.001$).

CONCLUSIONS: The direct cost of Medicare beneficiaries with T2DM who died from a CVD-related cause was significantly higher in the year leading up to their death, and highest during the 3-months immediately preceding and including death, compared to T2DM patients who did not die.

SPONSORSHIP: Boehringer Ingelheim.

E8 Impact of Long-Acting and Non-Long-Acting Insulin Utilization on A1c Among Type II Diabetics in a Medicaid Population

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BACKGROUND: Diabetes is a serious disease affecting more than 29 million Americans and is associated with severe comorbidities and adverse events. Twenty percent of the total healthcare spend in the U.S. is associated with the treatment of diabetes. Insulin therapy is the mainstay of treatment for type I diabetics and an add-on option for type II diabetics unable to achieve glycemic control with oral anti-diabetic therapy. Recently, the approval of basaglar, the first follow-on biologic for long-acting insulin, glargine, prompted a performance review of long-acting insulins. An outcomes analysis of medical, laboratory and pharmacy data was performed among those members who received treatment with either long-acting or non-long-acting insulins to provide support during formulary evaluation and the development of diabetic clinical programs and outreach.

OBJECTIVE: Compare the clinical impact of long-acting insulin therapy versus non-long-acting insulin therapy on A1c among type II diabetics in a Medicaid population.

METHODS: A retrospective review of pharmacy utilization for insulins with a date of fill between 7/1/2015-6/30/2016 (index period) was performed, and members identified. Medical claims with an ICD-10 of E11 during 2015 and 2016 was used to identify type II diabetics. Lab data with a date of service between 1/1/2015-6/30/2015 and 7/1/2016-12/31/2016 (evaluation periods) was reviewed to determine pre-A1c and post-A1c values. Members must have filled at least 90 days' worth of insulin within the last 120 days of the index period to be considered a current user. Members without a pre-A1c and post-A1c value were excluded. Members identified were placed into one of two cohorts: current long-acting users (LA) or current nonlong-acting users (NLA). NLA insulin was defined as all rapid, short, and intermediate insulins. Analyses were performed to determine the significance of A1c change between long-acting and NLA insulin users.

RESULTS: A total of 493 members were identified and placed into one of the two cohorts, 70% of which had a pre-A1c>8. Of the 493 members, 395 were LA users compared to 98 who were on NLA insulin. There were 269 LA users with a pre-A1c>8. A1c reduction for type II NLA users with pre-A1c>8 was statistically significant at an overall 12% reduction, or 1.2 point reduction in A1c per utilizer ($P<0.05$). Insulin type was found to not influence the probability of patient adherence ($P=0.3220$). Adherence, defined as MPR>0.8, was associated with higher odds of reduced A1c for type II diabetics with a pre-A1c>8 for all insulin types, but not at a statistically significant level ($P=0.6001$; OR 1.18; CI: 0.63-2.20). Although not significant, type II LA users who were adherent to insulin therapy saw a greater reduction in A1c compared to NLA users.

CONCLUSIONS: Despite a reduction in A1c, the use of LA insulin was not associated with a statistically significant reduction in A1c among those with an A1c>8; However, NLA use among type II diabetics with pre-A1c>8 saw a significant reduction in A1c and resulted in the lowest cost per utilizer. LA insulin was also found to not influence adherence.

SPONSORSHIP: None.

E9 Lower Hypoglycemia Risk and Better Persistence in Adults with Type 2 Diabetes After Switch to Insulin Glargine 300 U/mL Versus Other Basal Insulins in Real-World Clinical Settings

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BACKGROUND: In the EDITION 1 and 2 trials, patients (pts) with type 2 diabetes (T2D) on prior basal insulin (BI) and who received insulin glargine 300 U/mL (Gla-300) had similar glycemic control with less hypoglycemia compared with pts who received insulin glargine 100 U/mL (Gla-100).

OBJECTIVE: To compare the clinical outcomes of adult pts with T2D who were on prior BI and switched to Gla-300 or other BIs in a real-world setting.

METHODS: Retrospective pt-level data were extracted from the Optum Clinformatics database (October 1, 2014 to June 30, 2016). Pts had either ≥1 Gla-300 or ≥1 BI claim (Gla-100, insulin detemir, insulin degludec) from April 1, 2015 to March 31, 2016, defined as index BI claim, and ≥1 non-index BI claim (insulin NPH, insulin detemir, or Gla-100) at baseline (BL). Data were assessed at BL (6 months [mo] pre-index) and follow-up (FU, ≥3 mo post-index). We used generalized linear or logistic regression models to assess the effect of cohort on hypoglycemia incidence/number of events and A1C reduction, and Cox regression model for treatment persistence, with adjustment for BL demographic/clinical confounders. Hypoglycemic events were identified by ICD-9-CM/ICD-10-CM codes in medical claims.

RESULTS: This analysis included 1,204 pts who switched to Gla-300, and 616 pts who switched to other BIs. Compared with other BIs, pts switched to Gla-300 were older, mainly on Medicare advantage plans, had fewer comorbidities, higher mean insulin doses/day, were more likely to be on a glucagon-like peptide-1 receptor agonist or Gla-100, and had experienced fewer hypoglycemic events at BL. Mean BL A1C levels were comparable (Gla-300: 8.94%; other BI: 8.89%). Pts who switched to Gla-300 were less likely to experience hypoglycemia at 3-mo (OR: 0.56; 95% CI: 0.32-0.97; $P=0.039$) and 6-mo FU (OR: 0.58; CI: 0.38-0.87; $P=0.009$). Also, pts switching to Gla-300 had fewer hypoglycemia events from 0 to 3-mo FU vs. other BI (least squares [LS] mean: 0.58 (Gla-300); 0.78 (other BI); $P=0.037$), and were 34% less likely to discontinue BI during FU (HR: 0.66, CI: 0.54-0.81; $P<0.0001$). For pts with available A1C measures, reductions in A1C from BL to FU were modest but comparable for the cohorts (LS mean: −0.32% (Gla-300, n=492); −0.27% (other BI, n=242); $P=0.578$).

CONCLUSIONS: In real-world clinical settings, pts with T2D who were switched to Gla-300 had lower risk of hypoglycemia and better treatment persistence, but similar glycemic control, compared with pts switched to other BIs.

SPONSORSHIP: Sanofi U.S.

E11 Metabolic Outcomes for Type 2 Diabetes Patients on New Antidiabetes Classes Compared with Those on Traditional Classes in Central Texas

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BACKGROUND: According to the 2017 AACE/ACE Comprehensive Type 2 Diabetes (T2DM) Management Algorithm, new anti-diabetes classes (NAC: SGLT2i, GLP1-RA, or DPP4i) are preferred over more traditional anti-diabetes classes (TAC: SU, TZD, meglitinide) for dual therapy after initiation of metformin. Clinical trials suggest that NAC offer favorable effects on cardiovascular risk factors with non-inferior reductions in glycated hemoglobin (HbA1c) compared with TAC. This study evaluated the validity of this recommendation.

OBJECTIVE: To estimate and compare differences in HbA1c and weight reduction between NAC and TAC cohorts.

METHODS: This retrospective analysis of medical and pharmacy claims from the period 2013-2015 evaluated patients >18 years old with ICD-9 diagnosis of T2DM and use of TAC at least one year prior to first claim for a NAC (index date) or matched claim for a TAC for the index date ±14 days. Differences in HbA1c and weight reduction were evaluated between the NAC and TAC cohorts. Pre-index HbA1c, Diabetes Comorbidity Severity Index (DCSI), pre-index lag times, and post-index lag times were controlled in this analysis.

RESULTS: Data from 126 NAC and 373 TAC patients were analyzed (52% female; mean age [SD]; min-max), 58.71 (11.77; 24.00-85.00). Patients in the NAC and TAC cohorts had equivalent pre-index mean baseline HbA1c (9.1% vs. 8.9%, $P=0.194$). Adjusting for covariates, patients who took an agent in the new antidiabetic class (NAC) had significantly greater average -1.6kg weight reductions compared to those in TAC ($P=0.02$). In addition, mean HbA1c reductions were not significant between NAC and TAC cohorts ($P=0.49$) while also adjusting for covariates.

CONCLUSIONS: This real-world study demonstrated that addition of agents in the new anti-diabetes classes resulted in significant weight reductions compared with traditional anti-diabetes classes, while maintaining equivalent HbA1c reduction.

SPONSORSHIP: None.

E12 Factors Associated with Glycemic Control Among Patients with Type 2 Diabetes Enrolled in Medicaid

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BACKGROUND: Glycemic control among Medicaid enrollees with type 2 diabetes mellitus (T2DM) is generally poorer than commercially insured population. Yet, little research has sought to examine factors that contribute to glycemic control in Medicaid population. Understanding of those factors could be useful in designing more specific and effective interventions.

OBJECTIVE: Identify the factors associated with glycemic control among Medicaid enrollees diagnosed with T2DM.

METHODS: Using the medical claims, pharmacy claims and lab data from five Anthem Medicaid plans, a case-control study was designed among ≥18 years patients with T2DM who had two A1C results taken approximately six months apart during Jun 2013-Nov 2016. The outcome was defined as glycemic control (A1c<8%) based on the most recent A1c result. Demographic and clinical factors were measured during the six month prior to most recent A1c date. Association between glycemic control, and demographic and clinical factors after controlling for prior 6-month glycemic control (A1c<8%) was assessed using multivariable logistic regression model.

RESULTS: Compared to patients without glycemic control (N=1,798), those with control (N=4,386) were slightly older (mean age 53.2 vs. 51.6, $P<0.001$) and more likely to be female (64% vs. 61%, $P=0.02$). The patients with glycemic control had higher rate of primary care physician (PCP) visits (81% vs. 78%, 0.01), however, lower diabetes complications (43% vs. 57%, $P<0.001$), lower use of antidiabetic drugs (60% vs. 83%, $P<0.001$), insulin (6% vs. 22%, $P<0.001$), antihypertensives (55% vs. 63%, $P<0.001$) and anti-hyperlipidemics (54% vs. 60%, $P<0.001$) than those without control. In the adjusted analysis, the biggest predictor of glycemic control was prior control (adjusted odds ratio [aOR] 16.8, $P<0.05$). Other factors positively associated with glycemic control included: metformin use (aOR 1.54, $P<0.001$), antidiabetes drug adherence (1.94, $P<0.001$), PCP visits (1-3 visits vs. none aOR 1.50, $P<0.001$). Factors that were negatively associated with glycemic control include−insulin use (0.51, $P<0.001$), history of heart failure (0.68, $P=0.02$), and diabetes complications (1 vs. none aOR 0.73, $P<0.001$).

CONCLUSIONS: Among Medicaid enrollees with T2DM, we observed that prior glycemic control was an important predictor of future glycemic control. Interventions aiming to improve diabetes management among Medicaid enrollees should target plausibly modifiable factors such as metformin use, drug adherence and PCP visits.

SPONSORSHIP: Anthem.

E13 Clinical and Financial Outcomes of Switching Insulin Glargine to Insulin Detemir in an Ambulatory Care Services Countywide Health System

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PROBLEM DESCRIPTION: The cost of an insulin glargine vial for outpatient use increased over 7,000% from June to July 2015. A medication use evaluation showed switching from insulin glargine to insulin detemir would provide a significant cost savings. Although both products are long-acting insulin analogues, inherent differences in the insulins may lead to varying clinical outcomes.

GOAL: The purpose of this study was to examine the average A1c, total daily dose of insulin, and annual drug costs before and after the switch.

PROGRAM DESCRIPTION: In March 2016, the Harris Health System Pharmacy and Therapeutics Committee approved switching patients on insulin glargine to insulin detemir. Endocrinology, Internal Medicine, and Outpatient Pharmacies were involved with the planning and implementation phases of the conversion. To encourage the switch, the pen formulation of insulin detemir was added to the formulary. Additionally, insulin glargine was restricted and required a 6-month trial of insulin detemir. Education materials for physicians, pharmacy personnel, patients, and nurses were developed and distributed. Since patients had to be seen by their physician to make the switch, remaining refills for insulin glargine were honored until the patient was able to schedule an appointment with the physician over 3-6 months. Refill requests for insulin glargine were denied unless covered by third party insurance, which encouraged the physician to try insulin detemir. Pharmacy staff distributed educational "bag stuffers" to patients with the first prescription of insulin detemir, as appropriate. The initial dose conversion was 1 unit insulin glargine: 1 unit insulin detemir. Pharmacy provided patient information sheet and blood glucose log at time of conversion. Patients were seen in outpatient clinics 3-6 weeks after conversion to determine dosage adjustments. Tracked clinical measures include A1c and Total Daily Dose (TDD) immediately before and six months after switch. Drug quantity/costs of insulin glargine and insulin detemir were tracked monthly over a one year period.

OBSERVATIONS: The data collection form showed that the average A1c for patients on insulin glargine (pre-conversion) and insulin detemir (6 months post-conversion) were 9.2 and 9.9 respectively, $P=0.06$. The average Total Daily Dose (units/day) for patients on insulin glargine (pre-conversion) and insulin detemir (6 months post-conversion) were 61 and 66 units/day respectively, $P=0.47$. The total quantity for insulin glargine and insulin detemir pre-switch (March 2015-February 2016) was 41,399 vials compared to post-switch (March 2016-February 2017) of 55,871 pens/vials. The total annual drug costs for insulin glargine and insulin detemir pre-switch was $1,273,356 compared to post-switch of $828,238. The total annual savings was approximately $445,000.

FINDINGS/RECOMMENDATIONS: Based on a sample size of 4% (75 out of the total 1800 patients switched from insulin glargine to insulin detemir), the A1c and Total Daily Dose have increased (not statistically significant) since switching to insulin detemir. However, the financial outcomes seem favorable for the pharmacy drug costs, but further investigation is needed to see if this switch has negatively impacted clinical outcomes. The small sample size may be a limitation. Clinical pharmacists are still monitoring these patients which should correct and improve the clinical outcomes.

SPONSORSHIP: None.

E14 Real-World Effectiveness of Liraglutide Versus Sitagliptin Among Patients Enrolled in a Medicare Advantage Prescription Drug Plan

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BACKGROUND: Clinical trials in type 2 diabetes (T2D) have established that liraglutide provides sustained HbA1c reduction and superior glycemic control compared to sitagliptin. Studies have demonstrated cost-effectiveness of liraglutide when compared within and between classes. This has not specifically explored in a 65 and older population.

OBJECTIVE: To compare the effectiveness of liraglutide to sitagliptin on glycemic control and all-cause healthcare costs over a 1 year period among patients with a Humana Medicare Advantage Prescription Drug (MAPD) plan and T2D.

METHODS: This retrospective observational cohort study used administrative claims data considering the first prescription fill for either medication between 1/25/2010 and 12/31/2014 as the index date. The study included patients with an MAPD plan aged 65-89 years; with evidence of T2D; no evidence of type 1 diabetes; naive at baseline to insulin, GLP-1RA, DPP-4 and SGLT-2i; and with 6 months pre-index and 15 months post-index enrollment. Post-index persistence on index treatment and HbA1c results at baseline and 1 year (±90 days) were required. Inverse probability of treatment weighting using stabilized weights (IPTWs) was used to mitigate selection bias. Final IPTWs regression models adjusted for gender, race, health plan type, and level of prior antidiabetic medication on the primary outcome of change in mean HbA1c and secondary outcomes of glycemic control and costs, each at 1 year post index.

RESULTS: A total of 3,056 patients met selection criteria, 218 (7.1%) and 2,838 (92.9%) in the liraglutide and sitagliptin groups, respectively. The primary outcome was adequately powered to detect the difference in change in mean HbA1c between the groups at 1 year. The adjusted change in mean HbA1c was -0.42 in the liraglutide group compared to -0.12 in the sitagliptin group ($P<0.001$). The adjusted odds of a patient achieving the treatment goals of HbA1c < 7% and achieving an HbA1c reduction of > 1% were 1.68 times higher (95% CI: [1.25-2.24]) and 1.76 times higher (95% CI: [1.31-2.36]) for liraglutide compared to sitagliptin, respectively. The total healthcare cost in those achieving a treatment goal of HbA1c < 7% was not significantly different between treatment groups.

CONCLUSIONS: Without an increase in all-cause total healthcare costs, older adult patients taking liraglutide demonstrates significantly greater glycemic control and likelihood of control compared to sitagliptin over a 1 year period.

SPONSORSHIP: Novo Nordisk.

E16 Validation of an Algorithm to Identify Death in Administrative Claims Data

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BACKGROUND: Death data are not available in most insurance claims databases. For studies involving death as an outcome, many have relied upon a published algorithm by Joyce to identify death. Although this algorithm has been used in the literature, it has not been validated.

OBJECTIVE: Validate algorithms to identify all-cause and CV-related death in a T2DM population in Medicare database.

METHODS: Patients aged ≥65 years with a diagnosis for T2DM from 01/01/2013 to 07/31/2015 were identified from the 5% Medicare standard analytic file. Patients who died from 01/01/2013 to 09/30/2015 were identified using the death indicator available in the data (Medicare death) and via the Joyce algorithm (all-cause death). The algorithm defines death as a claim for an event likely to be fatal including (1) resuscitation (CPT-4: 92950); defibrillation (CPT-4: 9260, 9261); cerebral death (CPT-4: 95824); cardiac arrest/failure (ICD-9: 427.5x); evidence of injection given to stimulate the heart (HCPCS: J0170, J2000); kidney transplant failure/rejection (ICD-9: 996.81), transplant organ failure, non-specific (ICD-9: 996.80), cardiac complication (ICD-9: 997.1); or (2) a hospitalization, an emergency room visit, or ambulance service for any cause during the last month in

which medical claims were available; or (3) inpatient stay having a discharge status of "expired". Furthermore, we created a modified version of the Joyce algorithm (CV-related death) which was applied to identify CV-related death including; outpatient visits for resuscitation; defibrillation; cerebral death; cardiac arrest/failure; injection to stimulate the heart or hospitalization for acute myocardial infarct, unstable angina, heart failure, stroke, arrhythmias, cardiac arrest or revascularization procedure. The accuracy of the algorithms was evaluated by testing algorithm deaths against Medicare death, including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). PPV was used to evaluate accuracy of CV-related death algorithm.

RESULTS: A total of 521,931 patients were included. For all-cause death, the algorithm identified 72,129 deaths while Medicare death indicator identified 78,452 deaths. The sensitivity and specificity of the algorithm was 91.53% and 99.93%, respectively. The PPV was 99.55% and NPV was 98.52%. For CV-related death, 99.70% of CV-related deaths were Medicare death.

CONCLUSIONS: The algorithms to identify all-cause and CV-related death in a T2DM population achieved a high degree of accuracy in the Medicare database.

SPONSORSHIP: Boehringer Ingelheim.

E25 Budget Impact of Telotristat Ethyl in the Treatment of Patients with Uncontrolled Carcinoid Syndrome

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BACKGROUND: Carcinoid syndrome (CS) is a rare disease affecting cancer patients with metastatic neuroendocrine tumors that have spread to the liver and other organs from the gastrointestinal tract. Telotristat ethyl (TE) is a FDA-approved drug indicated in combination with somatostatin analog (SSA) therapy for the treatment of adults with CS diarrhea who are not adequately controlled by SSA therapy.

OBJECTIVE: To estimate the 3-year projected impact on the annual budget for a hypothetical 10 million-member U.S. health plan that reimburses TE in combination with SSA therapy for CS patients not adequately controlled on SSA therapy alone.

METHODS: An Excel-based budget impact model was generated using a deterministic Markov model that estimated the annual transition of CS diarrhea patients on current SSA therapy (octreotide LAR) across 3 health states (control, not adequately controlled, and dead), and costs associated with treatment of CS diarrhea including annual SSA and TE drug costs. The size of the eligible population in the hypothetical health plan was calculated based on the estimated prevalence of carcinoid syndrome (0.0042%) and the proportion of patients being uncontrolled on SSA only (39.9%). The monthly drug costs of octreotide LAR and TE were calculated as the products of the unit costs of each regimen and the average monthly dose received by patients. Per member per month (PMPM) were calculated based on the assumed market uptake of TE of 15%, 20%, and 25% for the hypothetical U.S. health plan in years 1, 2, and 3, respectively. Inputs were drawn from pivotal TE efficacy trial, real-world database analyses and published epidemiological literature. Sensitivity analyses were performed to assess uncertainty in model results.

RESULTS: The model estimated that a plan of 10 million members would include 168 patients eligible for TE each year. The net budget impact of adding TE to the formulary of a 10-million-member plan was $1,474,000, $1,837,000, and $2,312,000 in years 1, 2, and 3, respectively. The PMPM cost was estimated to be $0.01, $0.02, and $0.02 in years 1, 2, and 3 respectively. The results were most sensitive to the estimate of the average octreotide LAR dose used and the proportion of the CS patients who become uncontrolled.

CONCLUSIONS: Under current model assumptions, adding TE for the treatment of patients with uncontrolled CS diarrhea in combination with SSA therapy would result in minimal budget impact to a hypothetical 10 million member U.S. health plan.

SPONSORSHIP: Lexicon Pharmaceuticals.

E26 An Electronic Intervention to Improve Safety of Testosterone Replacement Therapy at San Francisco Veterans Affairs Health Care System

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PROBLEM DESCRIPTION: Use of testosterone replacement therapy (TRT) for age-related low testosterone and nonspecific symptoms of aging is increasing, but safety and efficacy has not been established. Research suggests patients are often prescribed TRT without baseline labs, routine lab monitoring, and documented signs and symptoms of hypogonadism, and some have contraindications to therapy.

GOAL: To evaluate an electronic intervention to enhance safety of TRT for hypogonadism in veteran patients at San Francisco Veterans Affairs Health Care System (SFVAHCS).

PROGRAM DESCRIPTION: A cohort of all SFVAHCS patients prescribed TRT for hypogonadism (n = 271) was identified using an internal clinical performance dashboard. A standardized safety review note was developed in alignment with national VA TRT drug use criteria. Included patients had a recently dispensed (within the past 3 months) TRT prescription at SFVAHCS at time of review. Patients prescribed TRT for transgender therapy or deceased were excluded. Retrospective chart reviews were completed July 2016 through March 2017 for included patients (n = 236). Individualized recommendations were communicated to the TRT prescriber via note in the electronic medical record. Outcomes of recommendations were measured May 2017.

OBSERVATIONS: Upon safety review, 119 patients (50%) had incomplete baseline labs; 80 (34%) incomplete annual monitoring labs; 66 (28%) no documented signs and symptoms of hypogonadism; 11 (5%) severe lower urinary tract symptoms or elevated prostate-specific antigen; and 5 (2%) severe untreated sleep apnea. A total of 231 patients (98%) had at least one safety recommendation made, and of those, 212 prescribers (92%) acknowledged the review note, 78 (34%) documented a follow-up plan, and 64 (28%) communicated the plan to the patient. At outcome review, prescribers discussed trial off TRT with repeat baseline labs in 20/119 patients (17%); ordered monitoring labs in 36/80 (45%); discussed hypogonadism signs and symptoms in 13/66 (20%); referred 2/11 (18%) to urology; and referred 0/5 to pulmonology.

FINDINGS/RECOMMENDATIONS: Consistent with previous research, SFVAHCS patients were frequently prescribed TRT without baseline labs, lab monitoring, and documented signs and symptoms of hypogonadism. A small portion had contraindications to therapy warranting specialist evaluation. These results demonstrate that healthcare system electronic interventions can be an effective strategy to conduct safety reviews, communicate recommendations to prescribers, and improve safety of TRT prescribing.

SPONSORSHIP: None.

E27 Characterization of Sustained Weight Loss in Clinical Studies: A Scoping Review of the Literature and Implications for Obesity Research

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BACKGROUND: There is little agreement on the definition of long-term sustained weight loss. Without such a common denominator, epidemiologic research on successful obesity treatment remains inconsistent and heterogeneous.

OBJECTIVE: To identify studies published since January 1, 2010 reporting on sustained weight loss in adults and to ascertain the most commonly accepted definitions and measures of sustained weight loss. The results of this study are intended to support and inform further research to develop an algorithm identifying intentional weight loss sustainers.

METHODS: Relevant English-language, peer-reviewed, full-length articles on weight loss studies with at least 1 year follow up and > 100 subjects were identified in PubMed, EBSCO (CINAHL, MEDLINE), ScienceDirect, and Google Scholar using key and U.S. Medical Subject Heading terms selected by subject matter experts and reviewed by the sponsor's librarian (e.g., sustained weight loss, weight reduction, weight loss maintenance, intervention, treatment outcome, etc.).

RESULTS: The analysis comprised 110 studies that met the inclusion criteria, out of 2,633 studies identified through the search strategy. Forty-six of the 110 included studies did not present a clear definition of sustained weight loss. The labels "sustained weight loss," "weight loss maintenance," and "long-term weight loss" were used in 58% of the studies (n = 64), the most common being "weight loss maintenance," used in 46% of the studies (n = 51). Thirty-one of those studies were randomized controlled trials, 5 were observational, and 13 were retrospective. Among 28 of 42 studies including a defined parameter for sustained weight loss in their definition, the most commonly used criterion included 5-10% sustained body weight loss. Most definitions of sustained weight loss were study-centric; that is, the amount of time for the weight loss considered to be "sustained" was based on the follow-up time period of the specific study and not a generalized definition. Only 44% of studies defined a weight maintenance period, with 1-2 years being the most common (n = 31 of 64 studies).

CONCLUSIONS: This review demonstrated a lack of consensus on a definition of sustained weight loss. A universal standard is needed for duration of weight loss and a clinically relevant amount of sustained weight loss. Creation of this type of standard would allow consistency in assessments and measurements, and lead to more meaningful and comparable research.

SPONSORSHIP: Novo Nordisk.

E28 Current Cholesterol Management in the United States and Changes from the Prior Year

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BACKGROUND: Cholesterol is initially managed by dietary and lifestyle changes, followed by pharmaceutical therapies. Many agents that treat hypercholesterolemia are generically available. Targeted therapies with higher prices have recently entered the market.

OBJECTIVE: To understand how U.S. health plans currently use their formularies to manage their members with hypercholesterolemia, hyperlipidemia and high trigylcerides and changes from prior surveys.

METHODS: Managed care medical directors and pharmacy directors completed an online interactive survey. Topics included: advisor and plan information, copays and drug/treatment usage of different classes for cholesterol management (classifying as: Unrestricted,1st tier, 2nd tier, 3rd tier, or requiring prior authorization [PA]).

RESULTS: The survey was completed by 52 MDs + PDs (11.3%): 55.8% were MDs and 57.7% worked for health plans/IDNs/PPOs/IPAs; 9.6% for PBMs; 3.8% for Government; the remainder consultants. Plans were National = 41.9%; Regional = 34.9%; or Local = 23.3%. Advisors/plans could cover multiple types of members: commercial (FFS = 54.2%; HMO/PPO = 70.8%), Medicaid (Traditional = 22.9%; HMO/PPO = 62.5%); Medicare (66.7%; Traditional = 22.9%; PDP-only = 45.8%) and Employer/Self-funded lives = 66.7%. Responses identified the highest PA rates were for: Proprotein Convertase Subtilisin/Kexin type 9 (PSCK9s) inhibitors (alirocumab and evolocumab) = 92.7% (84.6% last-year), lomitapide = 76.9% (71.1% last-year). Unlike most other cholesterol agents, PSCK9s are injected, require self-administration training, and subject to a specialty co-pays. Triglyceride, fibrate and niacin products were unrestricted (35.9%, 32.5%, and 30.8% respectively). Statins, with generic options were mostly first tier = 48.8%. Combination cholesterol-agents = 22.5% and cholesterol/cardiovascular combinations = 27.5% and were mostly in tier 2 (both previously ~20% higher in tier 2). While over-the-counter fish oil products and supplements were generally unrestricted in Medicaid plans, not covered by Commercial or Medicare plans, the prescription therapy icosapent was PA restricted by 28.2% of plans (previously 17.3%). The most common tier 2 products included ezetimibe (35.9% previously 40.4%) and the bile-acid sequestrants (27.5% previously 32.7%).

CONCLUSIONS: As new products enter the cholesterol management market, health plans will likely impose restrictions and plan designs on new classes favoring less expensive, generically available agents until real world effectiveness data becomes available.

SPONSORSHIP: TPG-National Payor Roundtable.

E29 Retrospective Analysis of Healthcare Utilization in Patients with Primary Mitochondrial Disease

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BACKGROUND: Primary mitochondrial disease is a heterogenous group of disorders characterized by impaired energy production as a result of mutations in the mitochondrial DNA or nuclear genes encoding mitochondrial proteins, which cause oxidative phosphorylation dysfunction. Primary mitochondrial myopathy (PMM) describes a large subset of primary mitochondrial disorders associated with muscle disease and can manifest as muscle weakness, muscle atrophy, and exercise intolerance.

OBJECTIVE: To understand healthcare utilization in patients diagnosed with PMD compared with the general covered patient population.

METHODS: This study was a retrospective claims analysis using Truven Health Analytics Marketscan Commercial and Milliman's proprietary commercial datasets. Patients of any age with an ICD-9/10) for PMD between 2008 and 2015 were included in the analysis. Specifically, ICD-9 277.87 disorders of mitochondrial metabolism and ICD-10 E88.40-E88.49 mitochondrial metabolism disorders, were used to identify claims related to PMD. Patients were included if they had at least six months of exposure after the first PMD-related claim occurrence, and either one PMD claim in the inpatient setting or two PMD claims in an outpatient setting. Claims are reported on

an allowed cost per member per month (PMPM) basis. Claims of PMD patients are compared to those of a general insured population.

RESULTS: During the study period, 3,825 patients between the ages of 0 and 15 (pediatric) and 4,358 patients between the ages of 16 and 65 (non-pediatric) were identified. Total allowed PMPM for pediatric patients was $4,829 and for non-pediatrics was $3,100 compared with an average of $202 and $486 for the total member population, respectively. The greatest resource utilization for patients diagnosed with PMD came from prescription medications, physician visits, home health and therapy. However the greatest drivers of costs based on allowed claims came from inpatient, surgery, prescription medications, and home health. Of note, there are no FDA-approved treatments for PMM, so drug costs could not be attributed to high-cost orphan-designation therapies.

CONCLUSIONS: Although PMD is a rare condition affecting approximately 1 in 5000 people, this retrospective claims study highlights the significant differences in the costs of medical care for PMD patients compared to those of a general population.

SPONSORSHIP: Stealth BioTherapeutics.

E30 Determinants of Adherence to Statin Medications for Patients in a Self-Insured, Employer-Sponsored Health Plan

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BACKGROUND: Studies regarding the adherence to cholesterol lowering medications within self-insured employee populations are limited. Treating dyslipidemia is the second most costly drug expenditure for the self-insured Butler University Employee Benefit Plan. HMG-CoA Reductase Inhibitors (statins) account for approximately 70% of those costs.

OBJECTIVE: To measure associations between prescription-specific and patient-specific factors and adherence to statins for patients enrolled in the Butler University Employee Benefit Plan.

METHODS: This is a retrospective, cohort analysis of pharmacy claims of 222 Butler University Health Plan patients for 2009-2012. Adherence was measured using the proportion of days covered (PDC) method. Adherence was defined a PDC rate > 80%. Eight variables were assessed as potential predictors of adherence to statins: number of comorbidities, gender, medication source (retail vs. mail order), number of different statins filled, prior statin user vs. new user, age, average copay amount, and income (inferred from median income from patient's ZIP code).

RESULTS: Fifty-four percent (121 out of 222) were adherent. In bivariate analysis, adherence was associated with older age (mean age = 59.8 years versus 55.5 for non-adherent, $P < 0.0005$), male gender (chi-sq = 5.63, $P = 0.018$), prior statin use (chi-sq = 5.27, $P = 0.022$), use of mail order pharmacies (chi-sq = 14.09, $P < 0.0005$), and higher average copayment ($27.82 per fill for adherent versus $19.28 for nonadherent). In a linear regression model, older age and mail order refill source were significantly associated with adherence, controlling for number of comorbidities, gender, number of unique statins prescribed, copayment amount, and income.

CONCLUSIONS: Many factors predict adherence to statins in bivariate analysis; only older age and medication source were associated with increased adherence in this population controlling for other factors. Findings will be used to develop clinical programs for patients at risk for decreased statin adherence.

SPONSORSHIP: Barry-Bashur Foundation.

E31 Identifying Sociodemographic and Clinical Predictors of Variable Statin Adherence Patterns Among Patients Enrolled in a Medicare Advantage Plan

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BACKGROUND: The benefit of statin therapy in reducing both primary and secondary atherosclerotic cardiovascular disease (ASCVD) is well-documented. Poor adherence remains a significant problem and is associated with increased costs and higher rates of adverse events. The proportion of days covered (PDC) is frequently used as a measure of adherence, with a PDC > 80% considered optimal. The PDC condenses longitudinal observations into a single value that cannot adequately depict different adherence experiences. Group-based trajectory models are designed to identify patients with similar longitudinal patterns and can depict the adherence experience while capturing its dynamic nature.

OBJECTIVE: The objective of this study was to characterize patients with similar statin adherence patterns and identify sociodemographic and clinical predictors associated with each trajectory.

METHODS: Patients enrolled in a Texas Medicare Advantage Plan from 1/1/13 to 6/30/16, with a statin prescription from 1/1/15 to 6/30/15, were included. Adherence was measured using a monthly PDC for 12 months. Patients were categorized into four adherence patterns using group-based trajectory modeling: high adherence (HA), rapid discontinuation (RD), adherence gap (AG), and gradual decline (GD). Multinomial logistic regression was performed to identify sociodemographic and clinical factors associated with each trajectory, with the HA group as reference.

RESULTS: 7,850 patients were included in the analysis, with 57.5% patients in the HA group. Females and incident users were more likely to fall into the three trajectories with low adherence. Speaking a language other than English was associated with an increased likelihood of falling into the GD and AG trajectories. Variables associated with one of the three trajectories included: Subsidy level (adjusted odds ratio [aOR]: 1.2 [CI: 1.1-1.4]) with the GD trajectory, Charlson Comorbidity Index (aOR: 0.9 [CI: 0.8-0.9]), and statin intensity (moderate vs. low, aOR: 1.3 [CI: 1.04:1-1.5]; high vs. low, aOR: 1.6 [CI: 1.3-2]) with AG trajectory. Variables associated with better adherence included age group 71-75 years and 90-day refills for two trajectories, RD and AG.

CONCLUSIONS: The predictors of the adherence trajectories determined can help identify potential non-adherent patients and their expected trajectory before they become non-adherent. Future research will focus targeting these patients with tailored interventions to improve their trajectory towards better adherence.

SPONSORSHIP: Regeneron Pharmaceuticals and Sanofi.

F00-F99 Mental and Behavioral Disorders
(e.g., Depression, Antipsychotics, Schizophrenia, Bipolar Disorder)

F1 Factors Associated with Initiation of Psychotherapy Among Medicaid Children Using Multiple Psychotropic Medications

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BACKGROUND: Psychotropic polypharmacy is common and increasing among children with mental health disorders despite concerns over its safety and efficacy. There is interest in combining psychotherapy and psychotropic medication since it is believed combined treatments may improve efficacy compared to psychotherapy or medication alone.

OBJECTIVE: To estimate the prevalence of psychotherapy among Medicaid children with psychotropic polypharmacy and to identify factors associated with initiation of psychotherapy.

METHODS: Anthem Medicaid claims data from 01/2013 to 06/2016 was used to identify patients aged 0-17 years with psychotropic polypharmacy (≥2 medication classes with ≥30 overlapping days). The case group (combined treatments group) included patients with polypharmacy and various types of psychotherapy; index date was assigned as the earliest psychotherapy date. The comparison group (medication only group) was assigned a random index date. Demographic, clinical, and treatment factors associated with initiating psychotherapy were measured within 6 months pre-index. Logistic regression was used to estimate relative contribution of each factor.

RESULTS: Of the 38,233 Medicaid children with psychotropic polypharmacy, 13,188 (34.5%) initiated psychotherapy while 25,045 (65.5%) did not. For the case group, the average number of psychotherapy visits was 6.3 over the 3 months following psychotherapy initiation (IQR: 2-8). The case group was slightly older, more likely to be female, and from Southern U.S. (all $P<0.001$). The case group had more co-occurring mental health conditions, higher levels of psychotropic polypharmacy (involving more medication classes), and a higher chance of receiving crisis services prior to start of psychotherapy (all $P<0.001$). In adjusted analysis, factors associated with initiating psychotherapy were history of crisis services (adjusted Odds Ratio (aOR): 4.86), ≥2 mental health conditions (aOR: 2.54), residing in Southern U.S. (aOR: 1.90), psychotropic polypharmacy involving ≥3 medication classes (aOR: 1.22; compared to 2 class polypharmacy), female sex (aOR: 1.20); all $P<0.001$.

CONCLUSIONS: Only a third of Medicaid children with psychotropic polypharmacy was observed to initiate psychotherapy. Our results indicate individuals with more complex psychotropic polypharmacy, more mental health conditions, and history of crisis services, were more likely to initiate psychotherapy. Further studies are needed to understand how two treatment approaches can be combined to maximize the treatment effect, especially among Medicaid children.

SPONSORSHIP: Anthem.

F2 Health Care Utilization and Costs Associated with Pharmacological Therapy Versus Nonpharmacological Therapy for Opioid Dependence

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BACKGROUND: Opioid-related poisoning deaths increased 4-fold from 1999 to 2014. The two main opioid use disorder (OUD) management strategies are pharmacological therapy (PT) using medication assisted therapy (MAT) and non-pharmacological therapy (NPT) without the use of medications. The most commonly used MAT agents are opioid receptor agonists (methadone [MET]), partial agonists (buprenorphine [BUP]), and antagonists (extended-release naltrexone [XR-NTX]).

OBJECTIVE: The objective of this retrospective observational cohort study was to compare health care resource utilization (HRU) and costs associated with PT or NPT for the treatment of OUD.

METHODS: Patients (≥18 years) with a diagnosis of OUD (ICD-9-CM codes: 304.0x, 304.7x; ICD-10-CM codes: F11.xx) between January 1, 2010 and December 31, 2015 were identified using the Truven Health MarketScan Commercial database. Patients initiating treatment with any PT (XR-NTX, BUP, or MET) between January 1, 2011 and December 31, 2014 were matched 1:1 using propensity score matching (PSM) with those treated with substance abuse counseling only (NPT). The first PT or NPT visit was defined as the index date. Patients were required to be continuously enrolled for medical and pharmacy benefits for 12 months before and 12 months after the index date (baseline and follow-up periods, respectively). Opioid and non-opioid related HRU and costs, including inpatient (IP) admissions, emergency department (ED), physician office, other outpatient (OP), and pharmacy visits, were evaluated in the baseline and follow-up periods.

RESULTS: A total of 23,108 patients (mean [SD] age 35.6 [12.5] years) received PT, compared to 6,883 (33.2 [13.43]) patients who received NPT only. PSM resulted in 5,275 patients in each cohort. There were no differences in the baseline demographic and clinical characteristics between the matched cohorts. During the follow-up period, patients receiving PT had fewer IP admissions (PT = 0.5 vs. NPT = 0.6, [$P<0.01$]) and OP visits (PT = 37.1 vs. NPT = 42.5, [$P<0.01$]) compared to those receiving NPT alone. There was no difference in ED visits across the two cohorts. Total direct medical costs in the follow-up period were significantly lower for patients in the PT cohort (PT = $23,003 vs. NPT = $25,626 [$P<0.01$]).

CONCLUSIONS: The higher acquisition costs for pharmacotherapies are offset by the lower inpatient costs in patients receiving PT, resulting in lower total costs during the follow-up period. Our results suggest that including medication in the treatment of OUD is cost-effective compared to counseling alone. Future studies are warranted to confirm these results.

SPONSORSHIP: Alkermes.

F3 Health Care Utilization and Costs Associated with Opioid Dependence Treatments

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BACKGROUND: In 2015, 2.6 million Americans aged ≥12 years had opioid use disorder (OUD). Two approaches for OUD management include medication assisted therapy (MAT) with opioid receptor agonists (methadone [MET]), partial agonists (buprenorphine [BUP]), and antagonists (extended-release naltrexone [XR-NTX]); or counseling alone (non-pharmacological therapy [NPT]).

OBJECTIVE: The objective of this study was to compare costs and health care resource utilization (HRU) among OUD patients treated with NPT or MAT.

METHODS: Adults (≥18 years) with a diagnosis of OUD (ICD-9-CM codes: 304.0x, 304.7x; ICD-10-CM codes: F11.xx) who initiated treatment with MAT (XR-NTX, BUP, MET) or NPT between January 1,

2011 and December 31, 2014 were identified using the Truven Health MarketScan Commercial database. The date of the first MAT claim or NPT visit was defined as the index date. Health care resource utilization and costs (inpatient [IP], emergency department [ED], physician office, and pharmacy visits) were evaluated for each cohort during 12-months baseline and follow-up.

RESULTS: A total of 1,041 patients prescribed XR-NTX, and 20,566, 745, and 6,883 prescribed BUP, MET, and NPT, respectively, were included. The mean (SD) age was 29.9 (10.93) for XR-NTX, 35.8 (12.46) for BUP, 37.9 (13.03) for MET, and 33.2 (13.43) for NPT. XR-NTX patients had significantly higher ($P<0.01$) Elixhauser comorbidity scores compared to the other cohorts (XR-NTX = 2.6 [1.57] vs. BUP = 2.0 [1.56], MET = 1.5 [1.48], NPT = 2.4 [1.70]). The percentage decrease in IP and ED visits from baseline to follow-up was greater for XR-NTX patients compared to the other cohorts: IP (XR-NTX = −46.6% [$P<0.01$], BUP = −20.8% [$P<0.01$], MET = −23.2% [$P=0.06$], NPT = −15.1% [$P<0.01$]); ED (XR-NTX = −26.1% [$P<0.01$], BUP = −13.3% [$P<0.01$], MET = −8.6% [$P=0.35$], NPT = −15.5% [$P<0.01$]). OP visits increased significantly ($P<0.01$) from baseline to follow-up for all groups (XR-NTX = +24.7%, BUP = +68.1%, MET = +195.2%, NPT = +92.8%). The percentage increase in total costs during the follow-up period was lowest and not significant for the XR-NTX group (+5%, $P=0.17$), whereas the increase was higher and significant ($P<0.01$) for all other groups (BUP = +43%, MET = +47.7%, NPT = +38.3%).

CONCLUSIONS: Although patients receiving XR-NTX were younger and had higher baseline comorbidities, the percentage increase in HRU and costs during the follow-up period were lower in XR-NTX patients compared to those receiving BUP, MET, or NPT, suggesting that the use of XR-NTX might potentially lead to lower HRU and costs in patients with OUD compared with other treatments. We suggest further studies to validate these findings.

SPONSORSHIP: Alkermes.

F4 Opioid Utilization and Cost: A 3-Year Look Among 15 Million Commercially Insured Members

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BACKGROUND: Heightened concern about prescription opioid use and misuse in the United States continues. In March 2016, the CDC released opioid prescribing guidelines encouraging prescribers to consider alternative pain therapy, lower doses and smaller opioid days supply per prescription. These guidelines along with more vigilant clinical programs and public health messages about the opioid crisis have likely made an impact on opioid prescribing. Recent reports have emerged demonstrating a decrease in opioid use for the first time in over a decade.

OBJECTIVE: Examine opioid utilization metrics in a commercial population over the last three years.

METHODS: Pharmacy claims between June 2014 and May 2017 (3 years) from 15.8 million commercially insured members were queried for opioid containing products. Buprenorphine/naloxone combination products and opioid containing cough and cold products were excluded from analyses. Opioid claims were further limited to solid dosage form products (i.e., tablets and capsules). Opioid utilization metrics were calculated monthly and included: (1) total paid amount per member per month (PMPM), (2) percent of members with an opioid claim, (3) quantity dispensed divided by days supply, (4) claims per capita, and (5) average morphine milligram equivalents (MME) per claim.

RESULTS: Over the 3 years, there were 25.4 million opioid claims accounting for over $1 billion total paid. All of the following results are reported for June 2014 and May 2017 and the June 2014 comparison to May 2017 expressed as the percent change. (1) total paid PMPM $1.71 dropped to $1.57, -8.3%, (2) percent of members with an opioid claim decreased 3.6% to 3.3%, -9.1%, (3) quantity dispensed divided by days supply 3.94 down to 3.73, a -5.2% change, (4) 4,752 opioid claims per 100,000 members and this dropped to 4,175 opioid claims per 100,000 members, -12.2%, and (5) average MME per claim started at 42.4 and decreased to 41.2, -3.0%.

CONCLUSIONS: As demonstrated by several metrics in this analysis, solid dosage form opioid use has decreased over the last 3 years in this large commercially insured population, with decreases in overall utilization outpacing decreases in measures of intensity per claim, such as quantity per day. Improving, developing and maintaining opioid misuse/abuse clinical programs should not wane. Insurers need to establish safe and effective opioid use criteria while ensuring members who need opioid therapy have access.

SPONSORSHIP: Prime Therapeutics.

F5 Real-World Health Care Cost of Substance Abuse for Patients Receiving Face-to-Face Therapy Versus Without Therapy

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BACKGROUND: Substance use disorders (SUD) are heterogeneous conditions characterized by recurrent maladaptive use of a psychoactive substance associated with significant distress and disability. Face-to-Face (FTF) therapy, either individually or in group settings, is one of the many treatment options available for SUD. This study aims to quantify the costs of SUD and differentiate between patients who received FTF and those that did not.

OBJECTIVE: Determine costs of care for mental health patients with SUD compared with non-SUD and compare SUD patients between those that receive FTF therapy and those that do not.

METHODS: This retrospective study analyzed medical and pharmacy claims data from 1/1/2011-7/31/2016 for Medicaid and commercially insured patients continuously enrolled for 6 months pre- and 2 years post-index date. The index date was the first medical claim with a diagnosis of mental health disorder. Qualifying patients were ≥18 years old with ≥2 paid medical claims. Each patient was categorized based on substance use (SUD or non-SUD). SUD patients were categorized according to receipt of therapy (FTF or non-FTF). For each category, patients were matched according to propensity scores and descriptive statistics were generated with means provided for continuous variables.

RESULTS: 14,072 commercially insured and 12,266 Medicaid patients met inclusion criteria. Mean 2 year total costs were $42,183 (SUD) and $29,764 (non-SUD; $P<0.001$) for commercial patients and $35,311 (SUD) and $32,946 (non-SUD; $P=0.003$) for Medicaid patients. Total costs were $43,325 (FTF) and $40,501 (non-FTF; $P=0.1696$) for commercial patients and $42,944 (FTF) and $36,591 (non-FTF; $P<0.001$) for Medicaid patients. Of the patients receiving FTF therapy, 44% and 22% in the commercially insured and Medicaid patients respectively received ≥12 sessions.

CONCLUSIONS: Behavioral health patients diagnosed with SUD are significantly more costly than non-SUD patients. Patients diagnosed with SUD receiving FTF have similar costs as patients not receiving FTF in the commercially insured population and higher costs than

patients not receiving FTF in the Medicaid population. Patients are receiving less than the recommended amount of FTF therapy for SUD treatment. Consequently, FTF therapy is not bending the cost curve. Options to help ensure adequate therapy could be of clinical benefit to patients and financial benefit to payers.

SPONSORSHIP: Pear Therapeutics.

F6 Determining the Economic Impact of Medication Nonadherence in Persons Treated with Depot-Injectable or Sublingual Buprenorphine for Opioid Use Disorder

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BACKGROUND: Previous analyses demonstrated that investigational flexible-dose, depot buprenorphine injection (CAM2038) is estimated to reduce direct medical costs versus sublingual buprenorphine (SL-BPN) in persons treated for opioid use disorder (OUD). Those analyses were based primarily on a recent 24-week Phase 3 clinical trial in which CAM2038 was compared to SL-BPN. However, the analyses applied 100% medication adherence in the SL-BPN group, which is not an optimal assumption given that up to 70% of SL-BPN patients may be non-adherent with their prescribed regimen at a given time and are more likely to relapse, which is manifested economically via increased healthcare utilization.

OBJECTIVE: To estimate differences in direct medical costs among OUD patients treated with CAM2038 or SL-BPN after adjusting for medication non-adherence.

METHODS: A Markov microsimulation modeled patient progression through OUD health states for 52 weeks. SL-BPN patients could be adherent or non-adherent with medication. CAM2038 patients could only be adherent while on treatment. Adherence was modeled based on trends reported in the literature for medication possession and diversion in an outpatient OUD treatment setting. Treatment retention was adjusted accordingly. The primary outcome was the difference in total costs between the two treatment groups. Alternative scenarios were used to evaluate input variability and structural assumptions on modeled outcomes.

RESULTS: In the most conservative scenario assuming approximately 10% non-adherence per month in the SL-BPN cohort, CAM2038 was associated with 21% lower direct medical costs. For every 1% increase in the proportion of non-adherent SL-BPN patients, the difference in direct medical costs between the cohorts increased by approximately 3%. Reductions in costs of inpatient hospital stays (-60% vs. SL-BPN) and emergency room visits (-56% vs. SL-BPN) were the primary contributors to the cost-savings for CAM2038. Findings were most sensitive to the assumed weekly proportion of non-adherent SL-BPN patients, and to assumptions regarding the time-dependency of medication non-adherence.

CONCLUSIONS: Investigational CAM2038 is expected to circumvent some medication non-adherence issues encountered with orally-administered OUD treatments. Accordingly, the economic benefits of CAM2038 may exceed those previously reported.

SPONSORSHIP: Braeburn Pharmaceuticals.

F8 Real-World Comparison of Treatment Patterns, Health Care Resource Utilization, and Costs in Schizophrenia Patients Treated with Long-Acting Injectable Versus Oral Antipsychotics

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BACKGROUND: Prior studies have suggested that compared to oral antipsychotics, long-acting injectable antipsychotics (LAIs) have the potential to improve adherence and reduce health care utilization. However, there are very few real-world studies comparing these outcomes between LAIs and oral antipsychotics.

OBJECTIVE: Our goal was to compare treatment patterns, health care utilization, and costs in schizophrenia patients treated with LAIs vs. oral antipsychotics.

METHODS: The MarketScan Multi-State Medicaid database was used in this analysis. Adults (≥18 years) having ≥2 LAI or oral antipsychotic prescription claims between 01 Jan 2011 and 31 Dec 2014 after first diagnosis of schizophrenia were identified. The date of the first LAI/Oral prescription was defined as the index date. Propensity score matching (PSM; 1:1) was used to control for differences in baseline demographic and clinical characteristics between the two cohorts. Medication treatment patterns, health care utilization and costs were assessed 12 months after the index date. Differences in outcomes between the two cohorts were evaluated using chi-square/t-tests (categorical/continuous variables), and Wilcoxon rank sum tests (utilization and costs).

RESULTS: Of 22,490 eligible patients, 2,896 (12.9%) were treated with LAI and 19,594 (87.1%) with oral antipsychotics. After PSM, there were 2,302 patients in each cohort and baseline characteristics were well balanced between the two cohorts. There was no difference in proportion of days covered between the cohorts, however patients on orals were significantly more likely to discontinue than those on LAIs (45.3% vs. 30.8%, $P<0.01$). Patients on LAIs had fewer inpatient admissions (0.5 vs. 0.9, $P<0.01$), hospitalization days (3.9 vs. 6.5, $P<0.01$) and ER visits (2.4 vs. 2.9, $P<0.01$), however had more prescription fills (29.5 vs. 25.3, $P<0.01$) over 12 months relative to those on orals. Patients on LAIs had similar overall costs ($P=0.35$), incurred $505 ($P<0.01$) higher monthly medication costs, and had lower monthly inpatient ($397 [$P<0.01$]) and ER costs ($17 [$P<0.01$]) compared to those on oral antipsychotics.

CONCLUSIONS: Antipsychotic discontinuation was common in schizophrenia patients, but these findings suggest that patients on LAIs were less likely to discontinue than patients taking oral antipsychotics. The discontinuation rate differences may account for reduced inpatient admissions. Hospital bed-day cost reductions offset the higher costs of LAI medications, thereby resulting in no increase in total health care costs relative to oral antipsychotics over 12 months.

SPONSORSHIP: Alkermes.

F9 Impact of Medication Changes During Hospital Stay on Postdischarge Hospital Readmissions and Health Care Charges: Analysis of Outcomes Among Adults with Schizophrenia or Bipolar Disorder Admitted to an Academic Neuropsychiatric Hospital

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BACKGROUND: Research suggests that atypical antipsychotic (AAP) therapy changes during hospitalization may adversely impact continuity of care among adults with serious mental illness. However, the potential impact of medication changes during hospital stay on subsequent 30-day hospital readmissions, as well healthcare costs is not well understood.

OBJECTIVE: To examine the rates of AAP medication change during hospital stay and their impact on (i) 30-day readmission rates and (ii) 180-day healthcare charges.

METHODS: This retrospective analysis of electronic health records within the University of Utah Clinical Enterprise Data Warehouse included patients ≥18 years. with an inpatient primary diagnosis of schizophrenia or bipolar disorder between January 1, 2010-December 31, 2015. A medication change was defined as any addition or discontinuation of an AAP between hospital admission and discharge. Two-part generalized linear models and logistic regression evaluated the impact of AAP medication changes on 30-day readmission rates and 180-day total (inpatient, outpatient, ER, and pharmacy) healthcare charges, controlling for demographics, comorbid conditions, index AAP, index year, and pre-index charges.

RESULTS: From a total of 3,820 adults with schizophrenia and bipolar disorder, 14% (198/1,450) and 11% (250/2,370) experienced a medication change, respectively. No significant differences in baseline demographic and clinical characteristics were observed between those with and without a medication change. Compared to adults without a medication change, likelihood of 30-day readmission was 84% and 154% higher among adults with a medication change for schizophrenia and bipolar disorder, respectively ($P<0.01$). Total healthcare charges during the 180-day follow-up period were higher for inpatients with a medication change than those without a medication change [$6,332 and $5651 higher for inpatients with schizophrenia and bipolar disorder, respectively ($P=0.01$)].

CONCLUSIONS: This retrospective study showed that medication changes during hospitalization resulted in higher 30-day readmissions and total healthcare charges. Further research is warranted to assess if the impacts of medication changes are specific to some AAPs and to understand the reasons for medication changes.

SPONSORSHIP: Sunovion Pharmaceuticals.

F10 Prescriber's Response to Noncompliance Information: A Claims-Based Analysis of Patients with Serious Mental Illness

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BACKGROUND: New technologies such as digital medicine offer prescribers the opportunity to monitor patients' medication adherence objectively and in a timely manner. Such information could potentially allow prescribers to tailor medical decision-making to better meet patients' needs, improve treatment response, and minimize spending on unnecessary, costly medications. However, the impact of access to such information on real-world treatment decisions is unknown.

OBJECTIVE: To determine how prescribers' knowledge of medication compliance affects changes in treatment patterns of non-adherent patients with serious mental illness (SMI) in a real-world setting.

METHODS: Using prescriber reported information on patient non-compliance from 2008-2015 health insurance claims data, we examined whether prescribers' documented knowledge of non-compliance was associated with different prescribing patterns for patients with SMI including schizophrenia, bipolar disorder and major depressive disorder. All patients in our sample initiated an oral atypical antipsychotic and were objectively non-adherent (proportion of days covered [PDC] <80%). The primary outcomes were the share of patients who increased antipsychotic dose, augmented treatment, switched antipsychotic medications, or used a long-acting injectable (LAI). The key independent variable was provider-documented patient history of non-compliance (ICD-9: V15.81).

RESULTS: Among the 286,249 patients with SMI who initiated an antipsychotic and had PDC<80%, 4,033 (1.41%) had documented non-compliance. When prescribers documented non-compliance, patients were more likely to be switched to another antipsychotic (32.8% versus 24.7%, $P<0.001$), have their dose increased (24.4% versus 22.1%, $P=0.004$), or receive an (0.09% versus 0.04%, $P=0.008$) but were less likely to have augmented therapy with another antipsychotic (1.1% versus 1.3%, $P=0.035$) than patients with no documented non-compliance.

CONCLUSIONS: Among patients with documented non-compliance, rates of switching and LAI use were higher and augmentation was lower compared to patients with no documented non-compliance. Access to adherence information may reduce extraneous spending as prescribers may avoid unnecessary, costly augmentation among patients who do not respond to therapy because of non-adherence.

SPONSORSHIP: Otsuka America Pharmaceuticals.

F11 Healthcare Resource Use and Cost with Brexpiprazole Use in Patients with Major Depressive Disorder

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BACKGROUND: Major depressive disorder (MDD) is the principal cause of disability worldwide and is a significant contributor to the total global burden of disease. Brexpiprazole is a serotonin-dopamine activity modulator that was approved in July 2015 in the U.S. as an adjunctive treatment for patients diagnosed with MDD and for treatment of schizophrenia.

OBJECTIVE: To describe healthcare resource use and costs before and after brexpiprazole use in patients with MDD.

METHODS: Patients with a brexpiprazole pharmacy claim and ≥2 medical claims with MDD diagnosis were identified from QuintilesIMS' PharMetrics Plus claims database between 10 July 2015 and 31 March 2016. The date of the first brexpiprazole claim was the index date. Patients with ≥6 months of continuous enrollment before (pre-index) and after (post-index) index were included. Resource use and medical costs were measured during the pre-index period and post-index periods.

RESULTS: The study included 844 MDD patients initiated on brexpiprazole. Patients had on average (±SD) 5.0 (±3.7) brexpiprazole fills (with average 31.5±7.7 day supply) during 6 months of follow up. Mean age was 47.2 (±12.7) years; 69.4% were female; 57.5% had commercial and 38.9% had a self-insured group health insurance as their primary payer; 87.0% were enrolled in PPO plan and 7.7% in HMO plan; 55.9% had comorbid anxiety disorder; and 46.8% were prescribed brexpiprazole by a psychiatrist. Patients used 1.8 (±0.9) antidepressants on average in the 6 months prior to brexpiprazole. The proportion of patients with an all-cause hospitalization decreased from 8.1% to 6.6% after brexpiprazole use; average length of stay per hospitalization decreased from 5.8 (±4.8) days to 5.5 (±3.6) days; average number of all-cause hospitalizations decreased from 0.12 (±0.51) to 0.10 (±0.43) per patient. The proportion of patients with an ED visit decreased from 18.1% to 16.9%; average number of all-cause ED visits increased from 0.28 (±0.73) to 0.30 (±0.96) per patient. The proportion of patients with an MDD-related office visit decreased from 85.5% to 84.2%; average number of MDD-related office visits increased from 6.99 (±11.16) to 7.40 (±11.63) per patient. Average total medical cost per patient was $6,803 (±$18,277) before and $6,421 (±$13,055) after brexpiprazole use.

CONCLUSIONS: Among patients treated for MDD, brexpiprazole use resulted in a lower trend in hospitalizations and approximate savings of $400 in total medical cost.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F12 Budget Impact Analysis of Long-Acting Injectable Aripiprazole Once-Monthly 400 mg in Bipolar I Disorder

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BACKGROUND: Long-acting injectable (LAI) aripiprazole once-monthly 400 mg/300 mg (AOM 400), an extended release injectable suspension of aripiprazole, is under clinical investigation for the maintenance treatment of bipolar I disorder (BP-I).

OBJECTIVE: This analysis evaluated the budget impact of introducing AOM 400 as a maintenance treatment for BP-I, using LAI risperidone, paliperidone palmitate, oral cariprazine, oral asenapine, and best supportive care (BSC) as comparator treatments.

METHODS: A budget impact model was developed from a U.S. payer perspective, using treatment-related, hospitalization, and adverse event (AE) cost estimates for a hypothetical 1,000,000-member health plan. The analysis examined three steps: (1) estimation of the number of patients eligible to receive maintenance treatment, (2) prediction of the proportion of eligible patients treated with the comparator treatments for each year of a 5-year time horizon, and (3) estimation of the costs associated with drug acquisition, hospitalization, and AEs for each treatment.

RESULTS: Assuming a prevalence rate of 0.6%, a cohort of 1,000,000 insured health plan members represents a population of 6,000 patients eligible for BP-I maintenance treatment. Market share for AOM 400 was predicted to increase from 0.6% in year 1 (current scenario) to 1.3% in year 5 (predicted scenario). Increased use of paliperidone palmitate and oral asenapine were also projected (from 2.1% to 4.1% and from 1.2% to 2.6%, respectively, in year 5), with a corresponding decrease in oral cariprazine and BSC. Treatment-related costs had the greatest impact on total budget increases, followed by AE management costs. Conversely, hospitalization costs had the greatest cost-saving impact. For the hypothetical cohort of 1,000,000 insured health plan members, per member per month (PMPM) incremental cost would range from $0.06 PMPM in year 1 increasing to $0.26 PMPM in year 5.

CONCLUSIONS: The model demonstrated that utilizing AOM 400 as a maintenance treatment for BP-I would result in a modest impact on a health plan's budget over a 5-year time horizon.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F13 Cost-Effectiveness Analysis of Long-Acting Injectable Aripiprazole Once-Monthly 400 mg in Bipolar I Disorder

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BACKGROUND: With the approval of new long-acting injectable (LAI) formulations in the maintenance treatment of bipolar I disorder (BP-I), cost-effectiveness is a concern for health plan decision-makers.

OBJECTIVE: This analysis evaluated the cost-effectiveness of aripiprazole once-monthly 400 mg/300 mg (AOM 400) in the maintenance treatment of BP-I versus the comparator treatments LAI risperidone, paliperidone palmitate, oral cariprazine, oral asenapine, and best supportive care (BSC).

METHODS: A Markov state transition model with yearly cycle lengths up to 74 years (patient's lifetime) was utilized based on evaluation of published economic models in BP-I, recommendations in a systematic literature review on U.S. economic models, and assessment of the available data for AOM 400. The target population included U.S. patients diagnosed with BP-I per the DSM-5 criteria, confirmed by the Mini International Neuropsychiatric Interview, and who maintained stability on AOM 400 for at least 8 weeks. The model considered all costs and outcomes from the U.S. healthcare payer perspective. Key outputs included total costs, quality-adjusted life years (QALYs), incremental costs and QALYs, and incremental cost-effectiveness ratios (ICERs). Future costs and health effects were discounted at a rate of 3%. Both probabilistic and deterministic sensitivity analyses were performed to access the robustness of the results to parameter uncertainty.

RESULTS: The cost per QALY gained with AOM 400 versus comparators ranged from $2,007 versus oral asenapine to being a dominant strategy (i.e., lower costs and better outcomes) versus oral cariprazine, LAI risperidone, paliperidone palmitate, and BSC. Patients treated with AOM 400 were estimated to have fewer hospitalizations and mood episodes per patient (5.37) than comparators (range 6.33 for oral treatments to 6.54 for LAI risperidone, 7.64 for paliperidone palmitate, and 8.93 for BSC) for a lifetime horizon. The sensitivity analyses demonstrated that the results were robust to parameter uncertainty.

CONCLUSIONS: These results showed that AOM 400 may be a cost-effective alternative in the treatment of BP-I for U.S. payers when compared to other treatments.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F14 Treatment Patterns and Healthcare Resource Use Among Patients Admitted with a Diagnosis of Major Depressive Disorder Who Are at Imminent Risk for Suicide

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BACKGROUND: Major depressive disorder (MDD) is associated with substantial economic burden, and patients hospitalized because of MDD have up to a 35% lifetime risk of committing suicide.

OBJECTIVE: The objectives of this analysis were to evaluate and compare healthcare resource use, admission and readmission measures among MDD patients with imminent risk for suicide receiving ECT vs. no ECT during their initial hospitalization.

METHODS: Using the Premier Perspective Database, patients admitted between 1/1/2010 and 9/30/2015 with a diagnosis of MDD and Suicidal Ideation or Suicidal Attempt were included in the analysis. The first hospitalization was defined as the index hospitalization. Two cohorts of patients were identified based on receipt of ECT during their index hospitalization. Demographics, clinical characteristics, medication usage and healthcare resource utilization were compared between the two cohorts. Hospital readmission rates during the 6-months post-index hospitalization were also compared between the cohorts. We hypothesized patients receiving ECT during their index hospitalization were refractory to anti-depressant treatments, were clinically more severe requiring excessive healthcare utilizations compared to those that did not receive ECT during admission.

RESULTS: A total sample of 190,272 was analyzed (mean age = 39 years, male = 43.5%). Overall, few received ECT (n = 2,265, 1.2%) and those who received ECT were older (mean age = 52 vs. 39 years, $P < 0.001$), married (35.1% vs. 21.7%, $P < 0.001$), Medicare covered (40.1% vs. 18.3%, $P < 0.001$), and were on Managed care (33.8% vs. 26.2%, $P < 0.001$). A higher proportion of patients who received ECT vs. no ECT, were taking comedications of any antidepressants (92.1% vs. 81.3%, $P < 0.0001$), atypical antidepressants (42.5% vs. 30.4%, $P < 0.0001$), antipsychotics (70.6% vs. 41.6%, $P < 0.0001$), and atypical antipsychotics (67.8% vs. 37.4%, $P < 0.0001$). The mean index hospital length of stay (LOS) was longer for patients who received ECT vs. no ECT (18.3 vs. 5.5 days, $P < 0.0001$). The mean total hospital cost for the index hospitalization was higher among patients who received ECT vs. no ECT ($24,579 vs. $7,022, $P < 0.0001$). The percentage of patients with any all-cause hospital readmissions was higher among patients who received ECT (30.5% vs. 23.6%, $P < 0.0001$).

CONCLUSIONS: The economic burden among patients with MDD with imminent risk for suicide is higher among patients who received ECT vs. no ECT potentially representing a more severe, and treatment refractory patients.

SPONSORSHIP: Janssen Scientific Affairs.

F15 Healthcare Resource Use and Cost Associated with Brexpiprazole and Quetiapine Extended Release in Major Depressive Disorder

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BACKGROUND: Brexpiprazole is a serotonin-dopamine activity modulator atypical antipsychotic (AAP) approved in July 2015 in the U.S. as an adjunctive treatment for patients diagnosed with major depressive disorder (MDD). Quetiapine extended release (XR) is an AAP approved in the U.S. in December 2009 as an adjunctive treatment in MDD.

OBJECTIVE: To compare real-world resource use and cost in patients with MDD treated with brexpiprazole and quetiapine XR.

METHODS: Patients with a brexpiprazole or quetiapine XR pharmacy claim and MDD diagnosis were identified in QuintilesIMS' PharMetrics Plus claims database between 10 July 2015 and 31 March 2016. The date of the first brexpiprazole or quetiapine XR pharmacy claim was the index date. Resource use and costs during the 6-month post-index period were compared between treatment groups in the overall (non-matched) population and between 1:1 propensity score (PS)-matched cohorts. Age, sex, region, payer type, plan type, prescriber specialty, comorbidity index, baseline all-cause healthcare cost, and MDD-related ED visits and hospitalizations, comorbid anxiety and hyperlipidemia, and number of ADTs used prior to index were used for PS matching.

RESULTS: 844 MDD patients initiated on brexpiprazole and 688 MDD patients initiated on quetiapine XR. All-cause hospitalization and ED visit rates were lower in brexpiprazole than quetiapine XR (hospitalizations: 6.6% vs. 12.5%; ED visits: 17.0% vs. 27.5%). Lower rates of hospitalizations and ED visits were associated with lower medical cost per brexpiprazole-treated patient ($2,124 lower (95% CI: -$3,785, -$463) compared to quetiapine XR. Average total cost including pharmacy cost was similar between the two groups: $13,821 (± 15,543) vs. $13,235 (± 22,293). 397 patients in each treatment group were PS-matched. Lower hospitalization and ED visit rates, and lower total medical costs were also observed in brexpiprazole compared to matched quetiapine XR patients (hospitalization 6.5% vs. 9.8%; ED visits: 18.6% vs. 21.9%). Average total medical cost per patient was lower by $2,884 (95% CI: -$5,046, -$721) in brexpiprazole. Average total cost including pharmacy cost was similar for brexpiprazole and quetiapine XR: $12,810 (± $12,760) vs. $13,693 (± $22,845).

CONCLUSIONS: A lower trend in hospitalizations and ED visits, and consistent and significantly lower medical costs were observed in patients with MDD treated with brexpiprazole compared to quetiapine XR in both overall and matched analyses.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F17 Evaluating Evidence for Antidepressants and Dextromethorphan and Quinidine in the Treatment of Pseudobulbar Affect

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BACKGROUND: Pseudobulbar affect (PBA) occurs secondary to neurologic conditions and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. A literature review assessing trials of antidepressants and dextromethorphan/quinidine (DM/Q) could facilitate understanding of the evidence supporting the effectiveness of these treatments for PBA.

OBJECTIVE: Review the evidence evaluating the treatment of PBA with either antidepressants or DM/Q.

METHODS: Trials were identified using prior systematic reviews as well as a targeted literature search that considered clinical trials and case reports and covered the time period since publication of the last systematic review. Search terms included PBA and other syndrome names, such as pathologic laughing and crying, emotional lability, emotionalism, and emotional incontinence.

RESULTS: This search identified 14 double-blind, placebo- or active-controlled studies, and 1 large open-label trial. Eight trials included more than 100 patients, including 5 DM/Q trials, and 1 trial each of fluoxetine, sertraline, and escitalopram. The large antidepressant trials recruited patients with multiple neuropsychiatric conditions; none specifically recruited patients with PBA (or synonymous condition). The FDA approval for DM/Q was supported by 3 controlled clinical trials (1 with an open-label extension), including patients with PBA secondary to ALS and MS, and a 52-week open-label safety study enrolling patients with PBA secondary to any neurologic condition. Also, a 90-day open-label postmarketing study was conducted in 367 patients with PBA and dementia, stroke, or traumatic brain injury.

CONCLUSIONS: No large, well-controlled studies specifically evaluated efficacy and safety of antidepressants to treat both PBA laughing and crying episodes. The larger antidepressant trials evaluated syndromes other than PBA, only evaluated PBA as a secondary outcome, or did not evaluate laughing episodes. Other limitations of antidepressant studies included data largely limited to stroke populations, use of nonspecific or unvalidated efficacy outcomes, incomplete safety reporting, and lack of defined PBA sample. DM/Q studies included consistent PBA definitions, systematic safety reporting and efficacy measures, and long-term safety evaluation across neurologic conditions and age groups, reflective of the level of rigor required for FDA approval.

SPONSORSHIP: Avanir Pharmaceuticals.

F18 Anxiety and Depression Symptoms and Every Night Sleep Medication Use in Older Adults in the United States

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BACKGROUND: The 2015 National Sleep Foundation Sleep Time Duration Recommendations in the United States advised 7 to 8 hours of sleep per night as conducive for health and well-being for adults 65 years and above. This recommendation is beset by the increased incidence of insomnia in older adults. Routine use of sedatives is an increasing concern in older adults globally. We were interested in using a U.S. nationally representative data set of older adults to quantify the relationship between self-reported anxiety and depression symptoms and every night use of sleep medications.

OBJECTIVE: To quantify the relationship between anxiety and depression symptoms and every night sleep medication use in a nationally representative sample of older adults in the United States.

METHODS: We conducted a case-control analysis to quantify via odds ratios (ORs) the association between subjects who reported experiencing symptoms of anxiety and depression and sleep medication use every night. Study subjects were from 2011 National Health and Aging Trends Study. Categorical responses were converted to the main outcome dichotomous variable to indicate sleep medication use every night of the week versus less than every night of the week.

RESULTS: Presence of each of the four anxiety and depression symptom exposures was associated with an elevated likelihood of nightly sleep medication use. For those that reported 'felt down, depressed, or hopeless?' nearly every day had an OR of 3.50 (95% confidence limit [CL], 2.28, 5.37) compared to those that experienced the symptom less frequently. Those that reported 'had little interest or pleasure in doing things?' nearly every day had an OR of 1.86 (95% CL: 1.32, 2.61) compared to those that experienced the symptom less frequently. Those that reported 'felt nervous, anxious, or on edge?' more than half the days had an OR of 3.43 (95% CL: 2.68, 4.37) compared to those that experienced the symptom less frequently. Those that reported 'been unable to stop or control worrying?' more than half the days had an OR of 2.91 (95% CL: 2.25, 3.77) compared to those that experienced the symptom less frequently.

CONCLUSIONS: Older adults that suffer from anxiety and depression symptoms are more likely to use sleep medications every night. Efforts should be undertaken to improve management of these anxiety and depression symptoms to possibly mitigate excess consumption of sedatives.

SPONSORSHIP: None.

F20 Adherence and Persistence on Long-Acting Monotherapy and Combination Therapy in Adults with Attention-Deficit Hyperactivity Disorder in the United States

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BACKGROUND: Maintaining treatment adherence and persistence to therapy are important for individuals to achieve optimal attention-deficit hyperactivity disorder (ADHD) symptom control over time. While long-acting (LA) stimulants are recommended for the treatment of attention deficit/hyperactivity disorder (ADHD) among adults, few studies have evaluated the real-world treatment adherence and persistence patterns among adults with ADHD receiving LA combination therapy (CT) or monotherapy regimens.

OBJECTIVE: To evaluate the one-year treatment adherence and persistence among commercially-insured adults with ADHD who received LA CT or monotherapy for ADHD in the United States (U.S.).

METHODS: Adults with ≥1 ADHD diagnosis and ≥1 LA ADHD medication were identified from the MarketScan claims database (4/1/2009-3/31/2014). The index date was randomly selected among LA medication initiation dates (index treatment). CT was identified if a different ADHD medication was filled within ≤30 days of the index date and the 2 medications overlapped ≥30 days; otherwise, the treatment was considered as monotherapy. Adherence was measured using proportion of days covered (PDC) during the 1 year post-index date, and defined as PDC≥0.8. Persistence was defined as time to discontinuation (TTD; i.e., ≥30 day supply gap). Adherence and persistence were compared between CT and monotherapy using multivariable logistic and Cox models, respectively, adjusting for baseline characteristics.

RESULTS: Of 225,600 eligible patients, 7.3% received LA CT and 92.7% received LA monotherapy (mean age: 29.0 vs. 31.0 years, respectively). LA CT patients had significantly lower adherence than LA monotherapy patients (mean PDC: 0.33 vs. 0.41; adherence rate: 7% vs. 16%, respectively; adjusted odds ratio: 0.38, $P<0.001$). LA CT patients also demonstrated a greater hazard of discontinuation and shorter median persistence compared with LA monotherapy patients (median TTD: 59 vs. 79 days, respectively; adjusted hazard ratio: 1.32, $P<0.001$).

CONCLUSIONS: Among U.S. adults with ADHD treated with LA medications, LA CT was associated with significantly lower adherence and persistence compared with LA monotherapy. Patients with low adherence/persistence due to multiple pill burden of LA CT may warrant transition to a LA monotherapy regimen that supports their symptom coverage needs.

SPONSORSHIP: Shire Human Genetic Therapeutics.

F21 Comparative Efficacy and Tolerability of Lisdexamfetamine Versus Other Treatments for Adults with Attention Deficit Hyperactivity Disorder: A Systematic Literature Review and Network Meta-Analysis

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BACKGROUND: Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder that can affect academic performance, well-being, and interpersonal relationships. Several pharmacotherapies are available for treatment of adults with ADHD; however, treatment decisions are challenging due to the absence of head-to-head clinical trials. In particular, payers are interested in the comparative efficacy and safety of lisdexamfetamine (LDX), the only branded long-acting stimulant in a generic-centered market.

OBJECTIVE: The study objective was to evaluate the efficacy and tolerability of LDX versus stimulants (dextroamphetamine, dexmethylphenidate, methamphetamine, and methylphenidate), non-stimulants (atomoxetine, clonidine, and guanfacine), and other medications (armodafinil, modafinil, suvorexant, and bupropion) for the treatment

of ADHD in the U.S. among adults (≥ 18 years) by means of a network meta-analysis (NMA).

METHODS: Relevant studies were identified by searching MEDLINE, EMBASE, Cochrane, the U.S. Clinical Trial Registry and relevant conferences. Study selection and data extraction were performed in duplicate. Study specific treatment effects regarding change from baseline at 12 weeks on the ADHD-rating scale-4 (ADHD-RS-IV) and risk of discontinuation were synthesized by means of random effects Bayesian NMAs. Relative treatment effects were expressed as mean differences in ADHD-RS-IV or hazard ratios (HRs) for discontinuations along with credible intervals (95% CrI).

RESULTS: The systematic literature review identified 113 randomized controlled trials. Results of the NMA suggest LDX was associated with the greatest reduction in ADHD-RS-IV versus placebo (-10.51; 95% CrI: -15.57,-6.27). LDX showed favorable treatment effect estimates versus all treatments, although reductions in mean ADHD-RS-IV scores were not statistically significant. Furthermore, LDX was associated with a smaller risk of discontinuation than all other treatments, except for mixed amphetamine salts. Sensitivity analyses exploring outlier trials with regards to various baseline patient characteristics did not have meaningful impact on results.

CONCLUSIONS: Based on currently available evidence, LDX is associated with the greatest reduction in ADHD-RS-IV relative to placebo and may provide greater efficacy and tolerability than generic treatments for adults with ADHD, supporting the use of LDX in the U.S.

SPONSORSHIP: Shire.

F22 Academic Detailing for Attention-Deficit/Hyperactivity Disorder in Oklahoma Medicaid

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PROBLEM DESCRIPTION: Recent CDC reports demonstrate no significant improvements in ADHD over-prescribing in the primary care setting. Over-prescribing of ADHD medications remain a significant issue for the Oklahoma Healthcare Authority (OHCA).

GOAL: Academic Detailing (AD) disseminates evidence-based, best practice guidelines. OHCA uses its AD program to (1) reduce ADHD medication prescribing, prescription costs, and prior authorizations; (2) improve patient outcomes; and (3) assess provider satisfaction with the AD program.

PROGRAM DESCRIPTION: Program information was obtained from the 2011 American Academy of Pediatrics Attention-Deficit/Hyperactivity Disorder (ADHD) guidelines. A pharmacist facilitated AD sessions, which involved discussions with prescribers focusing on practice paradigms for ADHD treatment and highlighting of potential benefits of guideline implementation. Sessions varied in attendance from one to eight prescribers and were performed from January 2016 to May 2017. A questionnaire regarding program satisfaction was given immediately after each session to all who participated.

OBSERVATIONS: ADHD prescribing observed through pharmacy claims declined ~9% in comparison to non-detailed providers. The predicted cost savings was $3,700 per provider detailed. ADHD medication prior authorization requests also declined by approximately 13% since detailing. Eighty individuals responded to the questionnaire. The majority were family practitioners (43%) and general pediatricians (22%) who spent on average 40% of their time caring for pediatric and/or ADHD patients. In regards to satisfaction, 75% reported they would make practice changes and 89% would recommend this program to colleagues and participate in future AD topics. In regards to session information 88% of respondents agreed it was relevant to their practice; 91% agreed it was evidence-based; 94% agreed it was new and/or different; 92% agreed it was easily understood; and 82% agreed it was clearly presented. More than 70% strongly agreed that the AD facilitator was knowledgeable and engaging.

FINDINGS/RECOMMENDATIONS: Providers who attended the program will likely continue to use AD services given their positive appraisal and response in their prescribing patterns. To demonstrate value, AD interventions that are measurable and provide meaningful benchmarks will facilitate justification of such services. Measurements that can elicit value are monitoring of prescription claims, costs, and prior authorizations as well as assessing provider satisfaction. Future considerations for the AD program include expanding to more providers and addressing other disease topics.

SPONSORSHIP: Children's Health Insurance Program (CHIP) Health Service Initiative, Pharmacy Management Consultants, and Oklahoma Healthcare Authority.

F23 Impact of a Coordinated Care Program on Costs and Outcomes of Children with Mental Illnesses in Mississippi Medicaid

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BACKGROUND: The Center for Advancement of Youth (CAY) is a multidisciplinary care coordination program that offers comprehensive diagnosis and treatment for children with behavioral or developmental issues in Mississippi.

OBJECTIVE: This study aimed to determine the impact of CAY on the costs and outcomes of children with mental illnesses enrolled in Mississippi Medicaid.

METHODS: A retrospective observational cohort study was conducted using 2014-2016 Mississippi Medicaid administrative claims data. In order to be eligible for the study, beneficiaries were required to have at least one claim for a newly diagnosed mental health diagnosis in 2015, be younger than 18 years of age at the end of the study period, and have continuous enrollment in Mississippi Medicaid between 6 months prior to their first mental health related visit (index) and the end of the study period. Only actively-managed CAY beneficiaries were included in the study. In order to be considered actively-managed, beneficiaries were required to have a visit to a CAY provider within 30 days of the index mental health visit, and at least two visits to a CAY provider in the post index period. Beneficiaries in the treatment and control groups were matched based on a propensity score, date and diagnosis of index mental health visit. Propensity scores were estimated based on beneficiaries' age, race, gender, region of residence, foster status, and number of mental health disorders in the 6-month pre-index period. Matched control group subjects were monitored from the date of their treatment counterparts' first meeting with CAY personnel through the end of the study period. Outcomes assessed included average days of hospital stay, number of doctor visits, number of psychosocial visits, number of emergency room visits, and all-cause healthcare cost. All outcomes were assessed for the entire post-index period and annualized to get per member per year estimates. Generalized linear models were used to assess the relationship between CAY group membership and each of the outcome variables.

RESULTS: The CAY group had significantly more doctor visits (5.72 vs. 4.61, $P<0.001$) fewer psychosocial visits (3.16 vs. 6.14, $P=0.002$), and lower total cost of care ($11,047 vs. $16,489, $P<0.001$) as compared to the non-CAY group. No significant differences were found on the number of emergency room visits and days of hospital stay.

CONCLUSIONS: This study demonstrates the beneficial impact of a multidisciplinary coordinated care program from the perspective of a state Medicaid program.

SPONSORSHIP: None.

F24 Academic Detailing Program Reduces Gaps in Care Within the Medicaid Population

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BACKGROUND: Despite the advancement in treatments and preventative strategies, cardiovascular disease (CVD) remains the leading cause of death in the U.S. It is known that the burden of CVD is higher among individuals with chronic mental illness. When compared with standard U.S. populations, persons with mental illness are more likely to die from CVD. Second-generation antipsychotics (SGA) have become a staple for treatment of many psychiatric disorders, replacing older agents due to their perceived advantages. However, weight gain, insulin resistance, hyperlipidemia and hyperglycemia are associated with use of SGAs. In response to their side effects, NCQA developed a HEDIS metric to assess the percentage of individuals within a health plan prescribed a SGA and receiving appropriate metabolic screenings. A pharmacist run academic detailing program was created to use clinical algorithms to identify providers whose patients were prescribed a SGA and had not received appropriate screenings. Interventions were conducted to engage providers and improve patient outcomes.

OBJECTIVE: To evaluate the clinical outcomes of a prescriber focused outreach program

METHODS: Clinical algorithms identified patients prescribed one or more SGA within a 90-day period without a paid claim for a fasting blood sugar, glucose test, HgA1C, comprehensive metabolic panel, or lipid panel within a year. Telephonic and face-to-face interventions were conducted with prescribers of identified patients, with the goal being to reduce gaps in lab tests of patients being prescribed a SGA. We performed a 6 month cross-sectional analysis where the consultation date served as the index date. As a proxy for continuous enrollment, patients that had 2 or more claims during the combined pre and post periods and with claims with a date of service that spanned 150 days or more were included. Patients without post consultation claims were excluded. Pre and post utilization of SGAs and distinct claim counts of recommended lab test were compared. Significance was calculated using the Wilconxon sign test with a significance threshold of $P<0.05$.

RESULTS: A total of 1,219 patient met the study inclusion criteria, resulting in 229 providers receiving a consultation. When comparing the pre and post periods, we observed an 188% increase in paid claims for recommended labs ($P\leq0.05$), resulting in a 40% reduction in gaps in lab tests. There was no significance difference in the number of paid claims for recommended labs when comparing the two modes of intervention: face-to-face visits (194%) and telephonic (187%; $P=0.3$).

CONCLUSIONS: Using clinical algorithms to identify and target prescribers has delivered positive results in reducing gaps in lab tests of patients receiving SGAs. The reduction in gaps can also positively impact the NCQA's HEDIS process metric.

SPONSORSHIP: Magellan Rx Management.

G00-G99 Diseases of the Nervous System

(e.g., Multiple Sclerosis, Migraine, Seizures, Restless Leg, Sleep Apnea)

G2 Physician Perceptions of Unmet Medical Needs in Huntington Disease in the United States

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PROBLEM DESCRIPTION: Huntington disease (HD) is a hereditary neurodegenerative disorder with chorea as one of its most prominent motor symptoms. Tetrabenazine (TBZ) has demonstrated efficacy in treating chorea in patients with HD, but is associated with neuropsychiatric side-effects, such as depression and anxiety, that may limit its clinical utility.

GOAL: To examine the unmet needs associated with TBZ as a treatment for HD-related chorea as identified by a survey of treating neurologists.

PROGRAM DESCRIPTION: Board-certified/board-eligible neurologists, in practice for ≥5 years and who treated ≥3 HD patients in the past 2 years, were recruited from an online physician panel to complete a cross-sectional survey. Potential respondents received a study invitation e-mail and completed the data collection form (~20 minutes). Physicians also provided information about themselves, their practice, general approaches to HD management, and perceptions of available treatment.

OBSERVATIONS: A total of 200 neurologists responded to the survey. Based on clinician responses, the most common reasons to treat chorea are impairment in the activities of daily living (54%) and quality of life (41%). Of patients with chorea who are prescribed a treatment, ~50% receive TBZ. When asked for their perception of chorea improvement on TBZ, more than half of physicians perceive TBZ as having minimal or no effectiveness. In addition to perceptions of insufficient efficacy, more than 40% of physicians agree that TBZ is not optimal due to side-effects or tolerability issues, and 51% of physicians agree that they are unable to titrate up due to side-effects or tolerability issues. Physicians also report side-effects leading to dose interruptions (reported by 33% of physicians as occurring "often" or "almost always") and reductions (30%). The most common side-effects that led to insufficient dosing and disruptions in titration were sedation and somnolence (41%), depression (24%), and anxiety (22%). Beyond the impact of side-effects on patient dosing, physicians and office staff report spending 1.5 and 2.2 hours, respectively, per patient per month managing TBZ-induced side-effects.

FINDINGS/RECOMMENDATIONS: The study findings emphasize that the practice patterns of physicians who treat HD-related chorea are influenced by tolerability concerns with TBZ, and highlight the need for alternate therapeutic options to TBZ with improved risk–benefit profiles for the treatment of chorea in HD patients.

SPONSORSHIP: Teva Pharmaceutical Industries.

G3 Healthcare Resource Utilization and Costs of Spinal Muscular Atrophy Care in the U.S. Medicaid Population

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BACKGROUND: Spinal muscular atrophy (SMA) is a rare neuromuscular disease characterized by progressive muscle atrophy resulting in respiratory, gastrointestinal, and orthopedic complications. It is a leading genetic cause of infant mortality with an estimated incidence in the United States of 8.5 to 10.3 per 100,000 live births.

OBJECTIVE: To characterize SMA in the U.S. Medicaid population: (1) evaluate the number and proportion of existing and new SMA cases over time, overall, and by state; and (2) examine the demographics and the healthcare resource use (HRU) of individuals with diagnosis claims for SMA.

METHODS: Used the U.S. Medicaid dataset from 1/1/2009-12/31/2012 (50 states). Primary outcomes included the number and proportion of existing and new SMA cases, HRU, costs, and treatment referral pathway. Descriptive statistical methodologies were utilized to analyze all outcomes.

RESULTS: AIM 1: The annual rate of existing SMA enrollees increased from 6.90 to 10.11 per 100,000 enrollees during 2009-2012. The overall rates for new SMA enrollees were lower in comparison; observed at a rate of 4.39 per 100,000 Medicaid enrollees, with a total of 2,186 new SMA cases throughout the study. AIM 2: All-cause HRU was examined during the follow-up period, 33.70% of the patients had ≥1 hospitalization and inpatient LOS was found to be 0.54 days (SD = 2.66) PPPM. The average number of monthly other therapy (ER, outpatient hospital, etc.) visits per patient was found to be 28.31 (SD = 57.49) A majority of monthly all-cause health care cost per patient was incurred by other therapy costs ($10,595.06) followed by inpatient stay ($1,868.00), long-term care visit ($855.41), and pharmacy costs ($763.58). Overall, the total average all-cause monthly health care cost per patient was found to be $14,082.04. Among several utilizations under "other therapy," the majority of the cost was incurred by home health services ($2,673.74), followed by private duty nursing services ($2,196.54) and DME utilization ($1,475.81) PPPM.

CONCLUSIONS: This is the first population-based study designed to identify and characterize new and existing cases of SMA in the overall U.S. Medicaid population and by individual U.S. states. Classifying the SMA population through resource utilization is valuable given the heterogeneity of SMA phenotypes and the individuals it affects from infants to adults. This data illustrates the economic burden in terms of resource utilization and health care costs faced by these patients and provides a foundation of information to guide medical and policy decision making.

SPONSORSHIP: Biogen.

G4 Comparison of Systematic Literature Review Inclusion Criteria and the Impact on Evidence-Based Treatment Recommendations: A Parkinson's Disease Psychosis Case Study

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PROBLEM DESCRIPTION: Managed care organizations are increasingly interested in comparisons of therapeutic interventions for which head-to-head clinical trials have not been conducted. Systematic literature reviews (SLRs) and indirect treatment comparison (ITC) studies have become critical inputs to decision-making. Inclusion criteria can have a significant impact on the resulting recommendations, as illustrated by two recent SLRs of treatment options for Parkinson's Disease Psychosis (PDP): SLR A, by the authors (funded by ACADIA) and SLR B, based on draft (2016) PD clinical guideline recommendations by the National Institute for Health and Care Excellence (NICE) in England.

GOAL: Compare two recent SLRs for PDP, and identify study inclusion criteria that contributed to different results and their implications.

PROGRAM DESCRIPTION: Study design choices were compared across the two studies include SLR inclusion/exclusion criteria, and the selection of clinical trial endpoints for indirect comparisons. The resulting evidence networks were charted. Study inclusion criteria that led to different findings and associated implications are identified.

OBSERVATIONS: Key differences in SLR inclusion and exclusion criteria were differences in target population and intervention definitions, which resulted in 23 publications being identified in SLR A compared to 10 in SLR B. Even among interventions considered in both, SLR A found three additional studies. SLR A strongly caveated findings from one study which was included without comment in SLR B: Fernandez 2009, which was designed as a sleep study and included only 8 patients in the quetiapine arm, 50% of whom dropped-out. While only SLR B conducted network meta-analysis, both studies examined common endpoints to determine which comparisons could be made. SLR B allowed for only psychosis specific endpoints, including pooled hallucinations and positive symptoms scales and the BPRS-hallucinations subscale, and did not consider broader psychiatric scales (e.g., Brief Psychiatric Rating Scale [BPRS] and Clinical Global Impression [CGI]) which SLR A identified as common endpoints across studies. As a result, SLR B did not include networks that could indirectly compare clozapine and quetiapine, whereas most of the networks considered in SLR A allowed for such a comparison.

FINDINGS/RECOMMENDATIONS: The two SLRs differ significantly in their conclusions regarding the efficacy of quetiapine and the relative efficacy of quetiapine compared to clozapine. Managed care decision makers should consider results of such studies within the context of study inclusion criteria.

SPONSORSHIP: Analysis Group.

G6 Comparison of Fall and Fracture Risk for Medications to Treat Alzheimer's Disease

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BACKGROUND: Anti-Alzheimer's disease (AD) medications are considered to reduce falls and fractures risk by improving gait performance. However, the evidence of comparative falls and fractures risk assessment across anti-AD medications are scarce.

OBJECTIVE: To compare the risk of falls and fractures across anti-AD medications among older Medicare beneficiaries.

METHODS: Using 2011-2013 Medicare claims data (5% sample), we identified older adults aged ≥65 years with AD based on validated algorithm. First observed date of prescription claim for an anti-AD medication [donepezil (D), galantamine (G), rivastigmine (R), and memantine (M)] was defined as the "index-date". Individuals with AD were grouped based on their first prescribed anti-AD medication. We excluded individuals who were not continuously enrolled in Parts A, B and D for six months before the index-date or had a fall or fracture (ICD-9-CM codes: E880-E888, 800-829) during six months period prior to the index date. These same diagnosis codes were used to identify outcomes of interest for falls and fractures. A Cox Proportional Hazards model was used adjusting for weights obtained from inverse

probability of treatment weighting (IPTW) and for any significant baseline covariates to control for residual confounding. Medicare beneficiaries were censored if they: (i) expired during the observation period, (ii) lost continuous Medicare eligibility; (iii) switched from the initial AD medication to another AD medication, or (iv) reached the end of study period (one year from the index-date).

RESULTS: The final study sample consisted of 7,452 (D: 4,750; G: 125; R: 983; M: 1,594) older Medicare beneficiaries with AD. The four groups were well balanced on observable characteristics after IPTW except for having Parkinson's disease and taking anti-Parkinson's medications at baseline. Total number of fall and fracture events in our study cohort during the one-year follow-up period was 1,231 (D: 785; G: 20; R: 181; M: 245). Using a Cox proportional hazards model adjusting for IPTW and baseline Parkinson's disease and anti-Parkinson's medications, estimates of hazard ratios, relative to D were 0.851, 1.042, and 1.202 for G, M, and R respectively; however, these were not statistically significantly different ($P = 0.13$).

CONCLUSIONS: Findings of this real-world study suggest no differences in risk of falls and fractures among anti-AD medications. Future larger scale studies are required to confirm this finding.

SPONSORSHIP: Alzheimer's Association grant (#2015-NIRG-342092).

G7 Healthcare Resource Utilization and Costs of Behavioral Disturbances in Dementia

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BACKGROUND: Common neuropsychiatric symptoms (NPS) such as agitation in patients with dementia/Alzheimer's dementia are challenging to families and adversely impact direct patient care, caregiver burden, and community resources. Yet there are few published studies evaluating the burden of agitation.

OBJECTIVE: Examine healthcare resource utilization and costs of agitation using available ICD-9 diagnosis codes in patients with dementia.

METHODS: Patients diagnosed with dementia (including Alzheimer's dementia) were selected from 6.3 million Medicare beneficiaries in the Truven MarketScan Medicare Supplemental and Coordination of Benefits 2012-2015 database. ICD-9 diagnostic codes were not available to identify agitation but existing behavioral disturbances (BD) ICD-9 diagnosis codes 294.11 or 294.21 were used as a proxy. Patients were ≥65 years old, with continuous medical and pharmacy benefits for ≥6 months pre- and post-index date. Index date set as date of dementia/AD diagnosis. Medical and pharmacy claims data used to analyze the clinical burden of BD, including comorbidities, HRU, and costs over the follow-up period. Descriptive analyses described resource utilization and costs in patients with and without BD.

RESULTS: 92,054 patients with dementia identified, of whom 17,351 (19%) had BD during follow-up. Mean age was approximately 83 years and mean follow-up was 17 months. Patients with BD had higher Charlson Comorbidity Index scores than those without BD (1.83 vs. 1.66). Per the Fillit 2002 late-stage disease severity criteria, inclusive of presence of decubiti, malnutrition, and aspiration pneumonia, 20% of patients with BD categorized as late-stage vs. 14% without BD. In patients with BD vs. without BD, mean number of hospitalizations was 0.74 (standard deviation [SD] 0.96) vs. 0.54 (SD 0.84), hospital days 5.05 (SD 10.69) vs. 3.16 (SD 8.41), and physician visits 7.54 (SD 9.88) vs. 10.88 (SD 11.66) during follow-up. Total costs per patient per year was $33,106 (SD $49,523) in patients with BD vs. $29,295 (SD $56,043) without BD, $P < 0.0001$.

CONCLUSIONS: Study describes the healthcare resource burden among patients with dementia and BD using one of the largest comprehensive patient sample available. Those with BD experienced higher number of hospitalizations and hospital days but fewer physician visits, potentially indicating inappropriate care in a population already experiencing challenges. While BD is a common occurrence, the rate obtained in our study is low, potentially indicating lack of proper diagnostic codes or symptom recognition or underreporting.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization.

G10 Comparative Effectiveness of Dimethyl Fumarate Versus Fingolimod and Teriflunomide on Annualized Relapse Rates in MS Patients Switching from First-Generation Platform Therapies in the United States

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BACKGROUND: Suboptimal responses in patients with multiple sclerosis (MS) receiving 1st-generation platform therapies (interferons or glatiramer acetate) may prompt treatment changes. Previous real-world comparative research of MS disease modifying therapies (DMTs) in the overall population has suggested dimethyl fumarate (DMF) to be comparable to fingolimod (FTY) and more efficacious than teriflunomide (TERI) in reducing relapses. However, there is limited comparative evidence in patients switching from platform DMTs in the U.S.

OBJECTIVE: To compare the annualized relapse rate (ARR) in MS patients who have switched from a platform therapy to DMF, FTY, or TERI.

METHODS: MS patients (18-64 years old) initiating an oral DMT from June 2013 to March 2015 were identified from the Truven MarketScan Commercial Claims Database. The index date was the date of first oral DMT fill. Patients were required to have: continuous enrollment in the database for 12 months pre-index date and ≥3 months post-index date; ≥1 MS diagnosis (ICD-9 code 340) over the pre-index period; discontinuation of a platform DMT with no evidence of oral or infusion DMTs over the pre-index period; and adherence to the index drug for ≥90 days. DMF patients were propensity-score matched (PSM) 3:1 to FTY and to TERI based on age, gender, region, an MS severity score (based on MS-related comorbidities), ARR, and number of hospitalizations over the pre-index period. Patients were censored when they dropped out of the database or at the end of the study period (March 2016). Post-index relapses were annualized.

RESULTS: The database included 20,311 oral DMT users. After applying the study criteria, the PSM yielded 833:279 switch patients for the DMF-TERI match. Patients were well-matched on all covariates: age (50 years for both), gender (76% vs. 75% female), MS severity score (0.86 vs. 0.99), and baseline ARR (0.23 vs. 0.30). Similarly, the PSM yielded 1602:534 switch patients for the DMF-FTY matched cohort. Patients were well-matched on all covariates: age (44 for both), gender (72% vs. 74% female), MS severity score (0.99 vs. 1.1), and baseline ARR (0.40 vs. 0.44). The standardized differences confirmed balance across all covariates for matched cohorts. The ARR over the follow-up period for DMF was 0.18 versus 0.28 for TERI ($P < 0.0001$) and similar for DMF and FTY (0.23 for both, $P = 0.291$).

CONCLUSIONS: In this analysis, the efficacy profiles for those oral DMT users specifically switching from platform therapies are consistent with findings from previous research conducted among all oral DMT users, regardless of prior therapy.

SPONSORSHIP: Biogen.

G11 Patient Versus Device-Reported Missed Injections with BETACONNECT Auto-Injector for Betaseron Therapy

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BACKGROUND: Adherence is defined by medication possession ratio (MPR) or proportion of days covered (PDC). Self-reporting is one way to evaluate if patients received medication accurately based on administration instructions. BETACONNECT is an electronic auto-injector used to deliver Betaseron (interferon beta-1b). As an alternative to self-reporting, the device captures patient adherence to a physician prescribed dosing regimen objectively by recording injection date, time, dose, and status each time a patient performs an injection. It does not rely on subjective measures such as patient recall or MPR which fails to account for actual drug administration.

OBJECTIVE: To assess differences in patient-reported adherence to therapy versus adherence captured by the BETACONNECT device.

METHODS: This study is a prospective, observational, multicenter, single-arm trial. Patients aged 18 or older diagnosed with RRMS or CIS were recruited from 19 neurology centers across the U.S. Patients newly prescribed or currently established on Betaseron therapy and naive to the BETACONNECT device were enrolled and followed for a 6-month observation period. Primary endpoints include adherence to Betaseron using BETACONNECT. Subjective adherence was derived via patient survey with a recall period of 6 weeks, and objective adherence was determined by projected injection count as per each patient's prescription versus actual injection count as captured by BETACONNECT over the same time period. Data from both device and patient reports were analyzed via descriptive analysis. Patient and device-reported adherence were matched by patient to attain match percentage between objective and subjective reporting methods.

RESULTS: 88 of 146 enrolled patients contributed adherence data for this interim analysis. 75 (85%) were previously receiving Betaseron therapy while 13 (15%) were naive to Betaseron. Expected injection count was 21 over 6 weeks for both cohorts. Device-reported adherence averaged 3.45 (SD, 4.32) missed injections over 6 weeks; 1.38 in naive and 3.81 in established patients. Patient-reported adherence averaged 0.95 (SD, 1.87) missed injections; 0.54 in naive and 1.03 in established patients. Overall, 49 (56%) patients under-reported number of missed injections on average by 23% (minimum 5%, maximum 81%).

CONCLUSIONS: Missed injections were under-reported by patients compared to the BETACONNECT device. Evidence suggests that patient recall is not a reliable measure of adherence although this needs further validation in future studies.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals.

G12 Injectable Disease-Modifying Therapies Cycling Versus Switching to Gilenya: A Retrospective U.S. Claims Study of Risk of MS-Related Relapses

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BACKGROUND: The introduction of the first oral disease modifying therapy (DMT), fingolimod (FTY), has enabled multiple sclerosis (MS) patients to achieve significant reductions in the risk of relapses and disability progression without the inconvenience and side effects associated with injectable disease modifying therapies (iDMTs) such as the interferons and glatiramer acetate.

OBJECTIVE: To compare relapse rates of patients switching from an iDMT to FTY against those of patients switching from one iDMT to another iDMT in a real-world setting.

METHODS: A retrospective cohort study was conducted using the MarketScan Commercial and Medicare Supplemental claim databases. Eligible patients were adults (ages 18-64 years) diagnosed with MS (ICD-9 340) who were treated with an iDMT for at least one year between 7/1/2011 and 6/30/2015 before switching to either fingolimod (switchers to fingolimod cohort) or another iDMT (iDMT cyclers cohort). The index date was the date of treatment switch; the prior twelve months were the baseline period and the subsequent twelve months were the follow-up period. Demographics, clinical characteristics, and medication use were assessed during the baseline and follow-up periods. MS relapses were detected based on a validated claims-based algorithm that takes into account health care visits and prescriptions for high dose oral or intravenous corticosteroids. Number of relapses in baseline and follow-up periods were computed. A negative binomial regression model with repeated measures was applied to estimate the incidence rate ratio of relapses over one year between the switchers to FTY and the iDMT cyclers.

RESULTS: Of 2,018 patients identified, 1,110 were switchers to FTY and 908 were iDMT cyclers. The cohorts were similar in age and gender, but more patients in the iDMT cyclers cohort had MS related symptoms and relapses in the baseline period. The negative binomial model indicated an incidence rate ratio of relapses (95% confidence interval) of 0.78 (0.61-0.99, $P=0.04$), a 22% reduction in risk of relapses associated with switching to FTY instead of switching to another iDMT.

CONCLUSIONS: In a real-world study of U.S. adults with MS who switched from any iDMT to either FTY or to another iDMT, the risk of relapses was significantly lower for those switching to FTY. This study provides real-world evidence to support FTY as an alternative treatment for patients on iDMT when a change in therapy is clinically indicated.

SPONSORSHIP: Novartis Pharmaceuticals.

G13 Time to Treatment Failure Following Initiation of Fingolimod Versus Teriflunomide for the Treatment of Multiple Sclerosis: A Retrospective U.S. Claims Study

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BACKGROUND: Disease modifying therapies (DMTs) for multiple sclerosis (MS) delay disease progression by reducing the frequency and severity of relapses. Limited data are available on the comparative

effectiveness of fingolimod versus teriflunomide, two oral DMTs commonly prescribed for the treatment of MS.

OBJECTIVE: To evaluate time to treatment failure among patients with MS who initiate fingolimod versus teriflunomide in real-world settings.

METHODS: A retrospective cohort study was conducted using MarketScan Commercial Claims data. Eligible patients were adults (ages 18-64 years) diagnosed with MS (≥1 inpatient claim or ≥2 outpatient claims ≥30 days apart with ICD-9 340.xx) who initiated fingolimod or teriflunomide between 9/12/2012 and 12/31/2014, and were continuously enrolled during the 1-year baseline period prior to treatment initiation (index date). Patients were followed from the index date until the first observed treatment failure, or until censoring at disenrollment or end of data. Treatment failure was a composite endpoint defined as the earliest occurrence of: MS relapse (identified using a validated claims-based algorithm); or treatment discontinuation (≥60-day gap in supply). Time to treatment failure was compared between the treatment groups through Kaplan-Meier analysis and a multivariable Cox regression model adjusting for baseline factors (age, gender, plan type, region, index year, treatment history with other DMTs, baseline number of MS relapses, and comorbidities).

RESULTS: The study included 3,078 patients treated with fingolimod (n=1,767; mean age=44.1, 78% female) or teriflunomide (n=1,311; mean age=50.9, 78% female). In the 1-year baseline period, the groups had similar frequencies of MS relapses (average of 0.4 relapses in both groups) and prior use of any DMTs (65% vs. 67%). Kaplan-Meier estimates of median time to treatment failure were 21.4 months with fingolimod versus 10.4 months with teriflunomide (log-rank $P<0.001$). After adjustment for baseline variables, treatment with fingolimod was associated with 41% lower hazards of treatment failure relative to teriflunomide (adjusted hazard ratio=0.59; 95% CI: 0.52-0.67; $P<0.001$).

CONCLUSIONS: In a real-world study of U.S. adults with MS, fingolimod was associated with lower risk of treatment failure compared with teriflunomide. These data should enable clinicians to consider real-world effectiveness when making treatment decisions regarding the choice of DMTs.

SPONSORSHIP: Novartis Pharmaceuticals.

G23 The Direct Costs of Seizures in Individuals with Selected Severe Childhood-Onset Epilepsies

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BACKGROUND: Direct costs of medical interventions for seizures in patients with severe childhood-onset epilepsies have not been well studied.

OBJECTIVE: Assess the direct costs for seizures requiring acute treatment in individuals with severe childhood-onset epilepsies.

METHODS: Commercial and Medicaid insurance claims records (Truven Health Analytics) from 2010-2015 were queried to identify patients with probable Lennox-Gastaut syndrome (LGS), Dravet syndrome or tuberous sclerosis complex (TSC) and at least 2 years of continuous insurance from date of first epilepsy/seizure diagnosis or AED prescription in the data period (index). Medical services and costs were evaluated for 2 years post-index for seizures requiring acute treatment identified from ICD-9 diagnosis codes in the following two categories: (1) Seizures without Injury requiring Emergency Department visit or emergent hospitalization, in which selected epilepsy or convulsion diagnoses codes were present and injury diagnosis codes were absent; costs were accumulated through hospital discharge; and (2) Seizures with Injury, treated in any setting, in which diagnosis codes for both epilepsy/convulsion (ICD-9 345.* or 780.3*) and injury were present. Injuries were classified as mild, moderate, or severe; all-cause costs were accumulated over 10, 30 and 90 subsequent days, respectively. Costs were annualized, normalized to 2017 dollars at 3% per annum.

RESULTS: A total of 9,799 patients were included in the study, 5,999 with LGS, 1,034 with Dravet and 2766 with TSC. Among LGS patients with Commercial insurance, average annualized cost of Seizures without Injury was $15,918, and ranged from $7,287 to $10,459 for Seizures with Injury, depending on severity. Among Medicaid LGS patients, Seizures without Injury cost $7,546, and from $3,300 to $16,582 for Seizures with Injury. Seizures without Injury cost $8,889 and $10,383 for Commercial Dravet and TSC patients, respectively, while costs were $4,838 and $5,263 for Medicaid Dravet and TSC patients. Corresponding ranges for Seizures with Injury were $2,379 to $10,169 and $5,218 to $8,382 for Commercial Dravet and TSC patients, respectively, and $3,005 to $5,543 and $1,346 to $15,102 for Medicaid Dravet and TSC patients, respectively. Patients with seizures had consistently higher all-cause costs than patients with no seizure activity.

CONCLUSIONS: This study provides analytical approaches to calculate the direct costs of treated seizures in both injured and noninjured patients. New therapies that reduce seizures could help to lower the considerable observed costs.

SPONSORSHIP: Greenwich Biosciences.

G24 Treatment Patterns and Healthcare Resource Use in Migraine Patients Newly Initiating a Preventive Treatment: Interim Results from the Assessment of TolerabiliTy and Effectiveness in MigrAINeurs using Preventive Treatment (ATTAIN) Study

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BACKGROUND: With the impending introduction of calcitonin gene-related peptide (CGRP) inhibitors to prevent migraine, it is important to understand real-world treatment patterns and migraine-related healthcare resource use (HRU) to identify any unmet needs.

OBJECTIVE: To describe treatment patterns and HRU in subjects initiating preventive migraine medication enrolled in a 6-month prospective observational study (ATTAIN).

METHODS: Episodic (EM) and chronic migraine (CM) subjects initiating preventive treatment at primary care or neurology clinics in the United States are being enrolled in ATTAIN, an observational study assessing tolerability and effectiveness of migraine preventive therapies. At baseline and monthly thereafter for 6 months, data from the sites and from patients on migraine frequency, treatment modifications, work productivity, and HRU are being collected.

RESULTS: The interim sample (n=123 completers) included 61 EM and 62 CM (both 50%) subjects; mean±standard deviation age 42±12 years; majority female (88%) and white (76%); mean age at first migraine diagnosis 23±12 years; 72% naive to preventive migraine treatment in the 5 years prior to enrollment. Baseline mean work productivity loss (WPAI) was 53%. In the 30 days prior to baseline, mean migraine days were 7±3 days for EM and 13±7 days for CM; most commonly used acute medications were triptans (57%) and nonsteroidal anti-inflammatories (50%). The most common preventive treatments initiated were antiepileptics (46%), tricyclic antidepressants (14%), and onabotulinumtoxinA (14%). Overall, 24-45% of

subjects decreased, skipped, stopped permanently, or increased use of preventive medication without medical advice. The main reason for stopping, decreasing, or skipping doses was to avoid side effects; main reason for increasing dose was perceived lack of efficacy. Over 6 months, 8 CM subjects reported a total of 12 hospitalizations, 9 requiring overnight stay; 3 EM subjects reported 4 hospitalizations, 3 requiring overnight stay. Emergency/urgent care visits were reported by 19 CM (total 22 visits) and 3 EM subjects (total 5 visits).

CONCLUSIONS: There is substantial treatment disruption in subjects initiating preventive migraine therapies mainly due to side effects and lack of efficacy. Despite considerable migraine burden, a majority of subjects were naive to preventive treatment. Further research is needed to understand reasons for non-initiation of preventives, rates of ER and hospitalization use, and the risk-benefit of existing preventives.

SPONSORSHIP: Amgen.

G25 Examination of Economic Burden and Healthcare Utilization of U.S. Patients with Migraine

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BACKGROUND: In addition to the direct medical costs, employers of individuals with migraine can bear an enormous burden due to lost productivity.

OBJECTIVE: Compare healthcare utilization and cost (HCRU) and direct, indirect, and societal (indirect + direct) costs between migraine and control patients.

METHODS: Adult migraine patients with 2 outpatient (OP) or 1 inpatient (IP) claim for migraine (ICD-9 code 346.x) and ≥1 pharmacy claim for migraine treatment before index (first migraine claim) were identified within MarketScan Commercial claims database from 1/01/2010-12/31/2013. For the subset of patients with health and productivity management data, productivity loss and indirect costs were estimated. Patients were continuously enrolled for 12-months prior to index and followed until IP death, end of continuous enrollment, end of absenteeism (ABS) or short-term disability (STD) eligibility, or end of study period. Migraine patients were propensity score matched to controls 1:1. Per-patient-per-month (PPPM) costs and HCRU were reported. Generalized linear models compared direct, indirect, and societal costs between migraine patients and controls.

RESULTS: A total of 26,647 migraine patients were matched to controls (mean age: 42 years; female: 67%-71%), of which 4,323 and 26,212 were matched for ABS and STD eligibility, respectively. Mean PPPM all-cause HCRU was higher among migraine patients with more IP admissions (0.01 vs. 0.001), OP visits (1.83 vs. 0.87), and pharmacy claims (1.95 vs. 0.67) than matched controls (all $P<0.001$). All-cause healthcare costs were significantly higher for migraine patients (total: $937 vs. $323; IP: $190 vs. $12; OP: $546 vs. $180; pharmacy: $201 vs. $131, all $P<0.001$). Migraine patients had increased indirect costs per month due to ABS ($354 vs. $291) and STD ($90 vs. $5) than matched controls (all $P<0.001$). Monthly societal costs due to ABS ($1,275 vs. $601) and STD ($1,037 vs. $309) were significantly higher for migraine patients (all $P<0.001$). After multivariate adjustment, annual direct costs ($13,032 vs. $3,234), and indirect costs due to ABS ($4,104 vs. $3,531) or STD ($1,131 vs. $52), were significantly higher in migraine patients than controls (all $P<0.001$). Annual societal costs associated with ABS or STD were also higher for migraine patients ($16,043 vs. $6,938; $14,278 vs. $3,182, respectively; $P<0.001$).

CONCLUSIONS: Migraine imposes high direct and indirect economic burden on payers and society due to significantly higher healthcare utilization and work productivity loss compared to controls.

SPONSORSHIP: Eli Lilly.

G26 Patient Preferences for Preventive Migraine Treatments: A Discrete-Choice Experiment

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BACKGROUND: Current preventive migraine medicines are associated with poor adherence and tolerability. There is an unmet need for effective migraine-specific preventive treatments with fewer adverse events (AEs).

OBJECTIVE: To understand treatment preferences of people with migraine and the relative importance of improvements in efficacy and avoiding AEs.

METHODS: In a web-based discrete-choice experiment survey, respondents who self-reported having ≥ 6 migraine days/month were offered choices between pairs of hypothetical preventive migraine medicines. Six attributes, informed by clinician input and two focus groups, defined the medicines: efficacy (10%, 25%, or 50% reduction in migraine days/month), daily function (No Improvement, 1-Category Improvement, 2 Category Improvement on a 5-point scale), cognition problems (None, Thinking problems, Memory problems), weight gain (0%, 5%,10% bodyweight increase), mode of administration (Daily oral pill, 2 times/month injection, once/month injection), and monthly co-payment ($5, $60, $175). Random-parameters logit was used to estimate preference weights and the results used to calculate willingness to pay for attributes changes.

RESULTS: The sample was 300 respondents (average age 41 years, 67% female, 66% had private insurance, average number of migraine days/month of 15.7, 86% had taken a prescription medicine to prevent migraines, 72% reported that migraines made physical activities difficult "All/Most of the time"). Among non-cost attributes, respondents valued a change from a 10% reduction in migraine days to a 50% reduction more highly than avoiding the worst levels of AEs, but were willing to tradeoff efficacy for fewer AEs. Avoiding memory problems was more important than avoiding thinking problems. Avoiding a 10% weight gain was more important than avoiding cognition problems. Respondents preferred a one-a-month injection and daily pill to twice-a-month injection. Respondents were willing to pay up to $116 for reduction in migraine days up to 50%, and between $32 to $84 to avoid adverse events such as thinking problems, memory problems and a 10% weight again.

CONCLUSIONS: The unmet need with preventive treatment in migraine is extremely high as reflected in the high willingness to pay for a substantial reduction in migraine days and to avoid AEs. Respondents valued reduced migraine days, but were willing to tradeoff efficacy to avoid AEs associated with current medications. The results suggest a preventive medication with fewer AEs would be valuable to some migraine sufferers.

SPONSORSHIP: Amgen.

G29 Migraine Treatment Patterns and Opioid Use Among Chronic and Episodic Migraine Patients Identified by a Clinician-Administered Semistructured Diagnostic Interview

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BACKGROUND: Chronic migraine (CM) remains suboptimally treated. Opioids have been used for acute treatment of migraine, but are not recommended for regular use due to the risks of medication overuse, tolerance, dependence, and opioid hyperalgesia.

OBJECTIVE: To describe migraine treatment patterns and opioid use in CM and episodic migraine (EM) patients.

METHODS: An observational study using retrospective claims data and survey data was conducted in a large medical group. Eligible patients were ≥18 years old, had ≥12 months of continuous medical and pharmacy enrollment prior to the screening date, and had ≥1 medical claim with a migraine diagnosis (ICD-9/10 code of 346.xx/G43.xxx) in the 12 months prior to the screening date. A Semi-Structured Diagnostic Interview (SSDI) administered by a trained clinician was used to determine if a patient had CM (≥15 headache days/month) or EM (<15 headache days/month). The SSDI included 31 questions related to headache symptoms, frequency, disability, medication use, and diagnosis. Acute treatment of migraine, preventive treatment of migraine, opioid use, and baseline characteristics were assessed for CM and EM patients based on claims data collected in the 12 months prior to the screening date. Results were summarized using descriptive analyses.

RESULTS: Of the 192 patients included, 129 had CM and 63 had EM. The CM cohort had a mean age of 49.4 years (SD=12.6) and was 93.8% female. The EM cohort had a mean age of 48.9 years (SD=15.4), and was 82.5% female. In relation to migraine treatment patterns, 67.4% of CM patients and 55.6% of EM patients had ≥1 claim for both acute and preventive medications. 53.5% of CM patients and 36.5% of EM patients also had ≥1 opioid claim ($P<0.05$); the mean number of opioid claims was 4.0 (SD=7.1) among all CM patients and 2.8 (SD=8.2) among all EM patients. Additionally, 33.3% of CM patients and 15.9% of EM patients had ≥3 opioid claims. The mean Deyo-Charlson Comorbidity Index scores were 0.3 (SD=0.7) for the CM cohort and 0.2 (SD=0.5) for the EM cohort. Furthermore, 13.2% of CM patients and 7.9% of EM patients had a diagnosis for a pain disorder other than migraine (e.g. psychogenic pain, central pain syndrome, chronic pain syndrome).

CONCLUSIONS: Approximately two-thirds of patients with CM filled prescriptions for both acute and preventive medications in the past year. The majority of patients with CM and about a third of patients with EM also received an opioid prescription in the same time period. Treatment patterns, including opioid use, in CM patients indicate opportunities for better management through improved care.

SPONSORSHIP: Allergan plc.

G30 Direct Costs of Chronic Migraine and Episodic Migraine in a Commercially Insured Population

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BACKGROUND: Published surveys have demonstrated higher headache (HA)-related direct costs for chronic migraine (CM) patients compared with episodic migraine (EM) patients. Little evidence exists regarding the real-world economic burden of CM and EM patients based on administrative claims data.

OBJECTIVE: The objective of this study was to assess the direct costs of CM and EM patients.

METHODS: CM and EM patients were identified from the Magellan Health administrative claims database with approximately 4.7 million patients. CM patients were identified based on having ≥1 CM diagnosis (dx) code (346.7x/G43.7xx) during the index period (1/1/11-12/31/14; date of the earliest claim=index date) followed by a second CM code 31-365 days after the index date. EM patients were identified based on having ≥1 non-CM dx code (346.xx/G43.xxx without 346.7x/G43.7xx) during the index period, followed by a second non-CM code 31-365 days after the index date. CM and EM patients were included if they were ≥18 years old on the index date and had continuous enrollment for ≥12 months both before and after the index date. EM patients were excluded if they had a CM dx code or an onabotulinumtoxinA claim with a migraine dx code (346.xx/G43.xxx) during the 12-month pre-index period, on the index date, or during the 12-month post-index period. Annual all-cause and migraine/HA-related direct payer costs (2015 dollars) were evaluated, using descriptive analyses, for both cohorts in the 12-month follow-up period (index date+364 days).

RESULTS: A total of 3,715 CM patients and 32,832 EM patients were included. The mean ages of CM and EM patients were 45 years (SD=11) and 44 years (SD=12), respectively. The percentages of female CM and EM patients were 84% and 83%, respectively. The baseline Deyo-Charlson Comorbidity Index scores for CM and EM patients were 0.52 (SD=1.04) and 0.43 (SD=0.95), respectively. Mean annual all-cause direct costs for CM and EM patients were $31,629 (SD=$51,514, median=$16,789) and $14,773 (SD=$33,943, median=$5,842; $P<0.05$), respectively. Mean annual migraine/HA-related direct medical costs for CM and EM patients were $7,805 (SD=$15,654, median=$2,857) and $1,672 (SD=$6,376, median=$285; $P<0.05$), respectively.

CONCLUSIONS: The CM cohort was associated with higher annual all-cause direct costs compared to the EM cohort based on unadjusted analyses. The CM cohort was also associated with higher annual migraine/HA-related direct medical costs compared to the EM cohort. Optimal management of CM is essential given the high economic burden of CM relative to EM.

SPONSORSHIP: Allergan plc.

I00-I99 Diseases of the Circulatory System
(e.g., Atrial Fibrillation, ACS, Pulmonary Hypertension)

I5 Comparison of Stroke- and Bleed-Related Events and Healthcare Costs Among Patients with Nonvalvular Atrial Fibrillation Newly Treated with Oral Anticoagulants

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BACKGROUND: Dabigatran is an oral anti-coagulant (NOAC) approved in the U.S. to reduce stroke risk in patients with nonvalvular atrial fibrillation (NVAF).

OBJECTIVE: Compare stroke- and bleed-related events and healthcare costs between dabigatran and rivaroxaban, and dabigatran and warfarin.

METHODS: Adult NVAF patients newly diagnosed and newly treated with dabigatran, rivaroxaban or warfarin were identified within MarketScan claims databases between 10/01/2010-12/31/2014. Patients were continuously enrolled for 12-months prior to index date (first NOAC claim) and followed for 12 months or until medication switch, discontinuation, inpatient death or end of data. Dabigatran patients were matched separately to rivaroxaban and warfarin patients in a ratio of 1:1. Proportion of patients with a stroke- or bleed-related event (i.e., hospitalizations) during follow-up was compared using Chi-square tests. Total costs consisted of stroke- and bleed-related inpatient and outpatient costs and reported as per-patient-per month

(PPPM). Generalized linear models compared stroke- and bleed-related costs within each comparison group, adjusting for demographics, baseline clinical characteristics, and baseline all-cause costs.

RESULTS: A total of 26,592 and 33,046 dabigatran patients were matched to rivaroxaban and warfarin patients, respectively (mean age 68 years; 37% female). Of those, 124 (0.5%) dabigatran patients and 134 (0.5%) rivaroxaban patients had a stroke-related event ($P>0.05$). PPPM stroke-related costs in dabigatran patients were similar compared to rivaroxaban patients ($51 vs. $57, $P>0.05$). A total of 273 (1.0%) dabigatran patients and 386 (1.5%) rivaroxaban patients had a bleed-related event ($P<0.001$). Compared to rivaroxaban, dabigatran patients had significantly lower PPPM bleed-related costs ($116 vs. $172, $P=0.001$). A total of 156 (0.5%) dabigatran patients and 208 (0.6%) warfarin patients had a stroke-related event ($P<0.01$). PPPM stroke-related costs in dabigatran patients were lower but not statistically different, compared to warfarin patients ($58 vs. $78, $P>0.05$). A total of 375 (1.1%) dabigatran patients and 512 (1.6%) warfarin patients had a bleed-related event ($P<0.001$). Compared to warfarin, dabigatran patients had significantly lower bleed-related PPPM costs ($94 vs. $138, $P<0.01$).

CONCLUSIONS: Dabigatran had similar stroke-related events and costs and significantly lower bleed-related events and costs compared to rivaroxaban, and significantly lower stroke-related and bleed-related events and costs compared to warfarin.

SPONSORSHIP: Boehringer-Ingelheim Pharmaceuticals.

I6 Physician Adherence to the 2013 ACC/AHA Statin Therapy Guideline Among Medicare Advantage Plan Providers

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BACKGROUND: Varying degrees of understanding of the 2013 ACC/AHA statin guidelines currently result in mixed patient outcomes and potentially unnecessary health care expenditures associated with cardiovascular disease.

OBJECTIVE: To examine physicians' responses regarding cholesterol management and determine their understanding of the 2013 statin prescribing guideline therapy recommendations using a theoretical framework.

METHODS: This study included physicians affiliated with a Medicare Advantage Plan (MAP) in Texas. A convenient sample of physicians responded to a self-administered questionnaire in August 2016. The questionnaire was developed from the Awareness to Adherence model (awareness-agreement-adoption-adherence) and focused on treatment recommendations from the 2013 ACC/AHA guideline. Physician demographic information was input from their provided NPI number. Other items assessed physicians' awareness of the ACC Statin Intolerance App, frequency of patient statin intolerance and rechallenge. Responses were measured using a five-point Likert scale ranging from 1-Strongly disagree to 5-Strongly agree. Descriptive statistics were conducted to determine the frequency of awareness, agreement, adherence and adoption. Chi-square tests were used to assess differences based on physician demographics.

RESULTS: A total of 215 responses were obtained and 197 were considered usable for analysis. Most physicians were White (62.1%), and family practice specialists (60.4%), based in the greater Houston, TX area (66.5%). Many (69%) were aware of the 2013 ACC/AHA guideline, however 79.9% had yet to adopt some facets (e.g., using LDL cholesterol as the target of therapy). Approximately 31% of responding physicians were aware of the ACC Statin Intolerance App and 58.4% were aware of the ACC Guideline Clinical App. Most physicians asked their patients about statin adherence (93.9%), initiated high-intensity statin therapy (70.1%), and rechallenged patients (59.9%) who were statin-intolerant. Overall adoption was significantly different across physician practice location ($P=0.024$), and guideline adherence was significantly different across race ($P=0.008$).

CONCLUSIONS: A high level of awareness of the 2013 ACC/AHA statin prescribing guidelines was observed among physicians; however, the level of adoption was comparatively lower. Education regarding adherence to the 2013 guideline and the variety of clinical tools (e.g., Statin Intolerance App) available for treatment recommendations is needed among family practice physicians.

SPONSORSHIP: Sanofi and Regeneron Pharmaceuticals.

I7 Budget Impact of Appropriate Aspirin Utilization for Primary and Secondary Cardiovascular Disease Prevention in the Managed Care Setting

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BACKGROUND: Cardiovascular disease (CVD) is the leading cause of death in the U.S. Low-dose aspirin therapy has been shown to reduce CVD events such as myocardial infarction (MI) and ischemic stroke. Aspirin therapy is recommended for CVD prevention in patients with previous CVD (secondary prevention) and in patients aged 50-69 years without prior CVD who have a greater than 10% 10-year CVD risk (primary prevention). Despite over-the-counter availability of aspirin, aspirin is underutilized for CVD prevention.

OBJECTIVE: The objective of this analysis was to evaluate the budget impact of appropriate low-dose aspirin utilization for primary and secondary CVD prevention.

METHODS: An economic model was developed from the payer perspective with a 1-10 year time horizon. The analysis examined aspirin utilization for both primary and secondary CVD prevention. CVD prevalence for MI, stroke and angina was used to determine patients with prior CVD (secondary prevention cohort). The 10-year CVD risk was used to estimate the number of patients aged 50-69 years for whom aspirin therapy is recommended for primary prevention. Costs in the model included the aspirin pharmacy cost and medical costs for ischemic stroke, nonfatal MI, GI bleeds and hemorrhagic stroke. The risk reduction with aspirin for reducing nonfatal MI, ischemic stroke and mortality was applied to the baseline risk by age. In patients taking aspirin, the increased risk for GI bleeds and hemorrhagic stroke was applied to the baseline risk of these events. The budget impact was calculated based on the total costs for patients within the plan assumed to be compliant with physician-recommended aspirin therapy compared to the total costs for the plan if all guideline-recommended patients were taking aspirin.

RESULTS: Over a 5-year time horizon in a plan with 1,000,000 members, appropriate aspirin utilization in the primary prevention cohort results in a savings of $4,155,466. In the secondary prevention cohort the appropriate utilization of aspirin results in a savings of $10,962,683. The total savings over 5 years for a plan in the primary and secondary prevention cohorts was $15,118,149. In both the primary and secondary prevention cohorts the cost of aspirin therapy

and the increased adverse event costs for GI bleeds and hemorrhagic strokes were more than offset by decreased costs for nonfatal myocardial infarctions and ischemic strokes.

CONCLUSIONS: Appropriate low-dose aspirin utilization for primary and secondary CVD prevention can result in significant cost savings for a managed care plan.

SPONSORSHIP: Bayer Healthcare Pharmaceuticals.

I8 Adherence and Persistence to Apixaban Versus Dabigatran, Rivaroxaban, and Warfarin in Adult Patients with Nonvalvular Atrial Fibrillation

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BACKGROUND: Non-vitamin-K oral anticoagulants are used, in conjunction with warfarin, for prevention of thrombotic events and strokes in patient with non-valvular atrial fibrillation.

OBJECTIVE: To assess adherence and persistence in patients with non-valvular atrial fibrillation newly initiating a direct oral anticoagulant (DOAC)—apixaban, dabigatran, or rivaroxaban—or warfarin.

METHODS: This was a retrospective, observational cohort study based on administrative claims from the MarketScan Commercial Claims and Encounters and Medicare Supplemental Databases. Patients selected for study were newly initiated apixaban, dabigatran, rivaroxaban or warfarin between 12/1/2012 and 9/1/2015; were aged ≥18 years at index; had continuous enrollment for 12 months pre- (baseline) and 6 months post- (follow-up) index; and had ≥1 baseline diagnosis of atrial fibrillation (without valvular heart disease). Adherence was measured as the proportion of days covered (PDC) with the index medication on hand during follow-up, and was dichotomized as adherent (PDC≥80%) vs. non-adherent (PDC<80%). Persistence was measured as the number of days from index until a >60 day continuous gap in days' supply without the index medication or the initiation of a class different than the index drug (non-persistence). Logistic regression (adherence) and proportional hazards regression (non-persistence) models were fitted, controlling for baseline demographic and clinical characteristics.

RESULTS: The study included 12,382 apixaban patients, 7,796 dabigatran patients, 25,337 rivaroxaban patients, and 29,452 warfarin patients. Apixaban patients had the highest PDC (76.1%) compared to dabigatran (66.3%), rivaroxaban (70.7%) and warfarin (70.9%, all comparisons $P<0.01$). Warfarin (OR 0.62, 95% CI: 0.59-0.66), rivaroxaban (OR 0.81, 95% CI: 0.77-0.85), and dabigatran (OR 0.55, 95% CI: 0.51-0.59) were significantly less likely to achieve adherence compared to apixaban. Patients using warfarin, rivaroxaban, and dabigatran, respectively, were significantly more likely to be non-persistent to their index medication during the 6 month follow up (HR 1.47 [95% CI=1.41-1.54]; HR 1.41 [95% CI=1.35-1.47], and HR 1.82 [95% CI=1.79-1.92]) compared to apixaban.

CONCLUSIONS: Adherence and persistence were significantly more likely in patients initiating apixaban than dabigatran, rivaroxaban or warfarin. These findings are important given the potential role of adherence in preventing costly downstream clinical events.

SPONSORSHIP: Pfizer and Bristol-Myers Squibb.

I9 Long-Term Healthcare Costs of Stroke and Bleeding Among Patients with Atrial Fibrillation Treated with Non-Vitamin K Antagonist Oral Anticoagulants

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BACKGROUND: Oral anticoagulants are used to prevent stroke in patients with non-valvular atrial fibrillation (NVAF); however, they also increase the risk of bleeding.

OBJECTIVE: To evaluate healthcare costs associated with ischemic stroke/systemic embolism (SE) and major bleeding in patients with NVAF treated with non-vitamin K antagonist oral anticoagulants (NOACs).

METHODS: A retrospective matched cohort design was used with Clinformatics Data Mart Database, a United States (U.S.) claims database. Adults with NVAF, who had ≥1 ischemic stroke or SE hospitalization claim were identified and the date of the first stroke/SE was termed the index date. A randomly selected index date was imputed for a cohort of adults without a stroke event and matched 1:1 to those in the stroke cohort based on propensity scores. Similarly, adults with and without major bleeding events were identified by a validated algorithm developed by Cunningham et al. (2011). Patients in all cohorts were required to have ≥1 NOAC dispensing overlapping with the index date, ≥12 months eligibility pre-index date (baseline), and ≥1 NVAF diagnosis. Healthcare costs, including hospitalizations, long-term care, home healthcare, rehabilitation centers, hospice, emergency room, outpatient, and pharmacy costs were assessed from the index date until the earliest date of the end of data availability, death, a switch to warfarin, or end of insurance coverage. Baseline characteristics were evaluated during the 12-month baseline period. Per patient per year (PPPY) costs were estimated and costs differences between the stroke and no stroke, as well as between the major bleeding and no major bleeding cohorts were calculated. Non-parametric bootstrapping was used to construct confidence intervals.

RESULTS: The mean follow-up period was approximately 1 year for both the stroke and no stroke cohorts (N=1,340 per group), and the major bleeding and no major bleeding cohorts (N=3,774 per group). Mean total healthcare costs PPPY were $81,414 and $32,607 for stroke and no stroke cohorts, respectively (cost difference PPPY=$48,807; 95% confidence interval [CI]: $42,117-$55,570); and $63,905 and $35,607 for major bleeding and no major bleeding cohorts, respectively; (cost difference PPPY=$28,298; 95% CI: $24,798-$31,471). Hospitalizations and other inpatient stays accounted for >50% of total costs for stroke ($57,668) and major bleeding ($38,073) cohorts.

CONCLUSIONS: Healthcare costs associated with ischemic stroke/SE appear greater than those associated with major bleeding for patients with NVAF treated with NOACs.

SPONSORSHIP: Janssen Scientific Affairs.

I10 Risk of Major Bleeding and Stroke in Nonvalvular Atrial Fibrillation Patients Adherent to Oral Anticoagulants

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BACKGROUND: The primary disease burden of atrial fibrillation (AF) is attributed to its association with an increased long-term risk of stroke, thrombotic events, heart failure and all-cause mortality.

OBJECTIVE: To compare the risk of major bleeding and stroke in non-valvular atrial fibrillation patients who were adherent to newly-initiated warfarin or direct oral anticoagulants (DOAC)—apixaban, dabigatran, or rivaroxaban.

METHODS: This was a real-world observational cohort study based on administrative claims from the MarketScan Commercial Claims and Encounters and Medicare Supplemental Databases. Patients were newly initiated on apixaban, dabigatran, rivaroxaban or warfarin between 12/1/2012 and 9/1/2015; aged ≥18 years at index; had continuous enrollment for 12 months pre- (baseline) and had ≥1 baseline diagnosis of atrial fibrillation (without valvular heart disease). All patients were followed until index drug discontinuation, switch, disenrollment or end of the study period. Cox proportional hazards models, adjusting for baseline demographics and clinical characteristics and with treatment as an independent variable, were used to compare the risk of both outcomes in patients who were adherent to their index oral anticoagulant (≥80% percent of days covered [PDC]).

RESULTS: The study included 19,449 adherent apixaban patients, 3,911 adherent dabigatran patients, 15,628 adherent rivaroxaban patients, and 15,653 adherent warfarin patients. Patients who were adherent to rivaroxaban or warfarin, respectively, had significantly greater risk of major bleeding than patients adherent to apixaban (HR 1.85, 95% CI: 1.51-2.27; HR 1.97, 95% CI: 1.59-2.44). Adherent dabigatran or warfarin patients, respectively, had a significantly greater risk of stroke compared to apixaban adherent patients (HR 1.53, 95% CI: 1.05-2.25; HR 1.67, 95% CI: 1.23-2.30).

CONCLUSIONS: In patients adherent to initial oral anticoagulant, apixaban was associated with a significantly lower risk of major bleeding than rivaroxaban or warfarin and, a significantly lower risk of stroke than dabigatran or warfarin.

SPONSORSHIP: Pfizer and Bristol-Myers Squibb.

I11 Comparison of Stroke, Venous Thromboembolic Events, and Other Outcomes for Patients with Nonvalvular Atrial Fibrillation Treated with Novel Oral Anticoagulant Agents or Warfarin

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BACKGROUND: Anticoagulants are recommended in patients with atrial fibrillation (AF) to prevent stroke and venous thromboembolism (VTE). Warfarin, the standard oral anticoagulant treatment, has a narrow therapeutic index that requires frequent laboratory monitoring. Novel oral anticoagulants (NOACs) have advantages including no blood monitoring requirements and fewer interactions; however, few studies have compared the real-world effectiveness of NOACs as a class to warfarin.

OBJECTIVE: To compare patients with AF initiating NOACs versus warfarin on clinical outcomes including stroke, VTE, bleeding events, and cost of care.

METHODS: This real-world retrospective observational study utilized Medicare Advantage Prescription Drug and fully insured commercial claims from the Humana Research Database. Patients were included if they initiated a NOAC or warfarin from January 1, 2012-September 30, 2015. Date of the first prescription of NOAC or warfarin was the index date. Patients were required to have two diagnoses for AF (ICD-9-CM: 427.31) on or during the 365 days prior to the index date (baseline period), ≥12 months of pre-index and ≥31 days of post-index enrollment, CHA2DS2-VASc score (risk score for stroke) of ≥2 and no oral anticoagulant use during the baseline period. Patients in the NOAC and warfarin groups were matched on propensity scores. Clinical outcomes and costs adjusted for censoring using Lin's interval method were compared in the matched groups using Cox proportional Hazards models and paired t-tests, respectively. Patients were censored at occurrence of the clinical outcome, end of enrollment or study period, and discontinuation or switch of index medication.

RESULTS: Patients on NOACs had a significantly lower risk of ischemic stroke (hazard ratio [HR], 0.81; 95% confidence interval [CI], 0.72-0.90), hemorrhagic stroke (HR, 0.66; CI: 0.47-0.92), VTE (HR, 0.56; CI: 0.45-0.68), and composite outcome of stroke or VTE (HR, 0.74; CI: 0.67-0.81) compared to patients on warfarin. Bleeding risk was similar in the two groups (HR, 0.91; CI: 0.76-1.09). Annualized medical and total costs were lower in the NOAC group compared to the warfarin group. Adjusted costs were also significantly lower in the NOAC group (NOAC vs. warfarin all-cause costs, $29,112 vs. $39,755; $P<0.001$).

CONCLUSIONS: Based on this study, NOACs appear to be an equally safe and potentially more effective alternative associated with cost savings in comparison to warfarin for managing patients with AF.

SPONSORSHIP: Janssen Pharmaceuticals and Humana.

I12 Reduction in Hospitalization and Medical Costs Among Patients Initiated with Sacubitril/Valsartan: Insights from an Administrative Database in the United States

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BACKGROUND: In the PARADIGM-HF trial, sacubitril/valsartan (SAC/VAL) was superior to enalapril in reducing the risks of cardiovascular death and heart failure (HF) hospitalization in patients with HF and reduced ejection fraction; however, early (3-month) hospitalization and healthcare costs following SAC/VAL initiation have not been examined in a real-world setting.

OBJECTIVE: To compare hospitalization and costs in the 3 months pre- and post-SAC/VAL initiation.

METHODS: De-identified claims data of adults enrolled in a large managed care health plan (commercial and Medicare Advantage [MA]) were used from Oct 2014 to Sep 2016. First SAC/VAL pharmacy claim during Oct 2015 to Jun 2016 was identified. Three-month pre- and post-index hospitalizations and costs (combined health plan plus patient paid amounts) were calculated. Hospitalizations and costs were compared between periods using McNemar and paired t-tests.

RESULTS: A total of 606 patients treated with SAC/VAL were identified (median [IQR] age, 71 [18] years; 77.7% MA enrollee; 67.8% male; 33.0% renal disease; 10.9% liver disease; 86.6% hypertension; 43.2% atrial fibrillation; 14.2% myocardial infarction [MI]; 71.6% non-MI ischemic heart disease). Compared to the 3-month pre-index period, the percentage of patients who experienced 3-month post-index HF hospitalization was lower (7.3% vs. 12.7%, $P<0.001$), though there was not a statistically significant difference in all-cause hospitalization (12.5% vs. 16.0%, $P=0.050$). Compared to pre-index, patients incurred non-significantly lower mean (SD) post-index (all-cause) hospitalization costs of $2,374 ($11,465) vs. $3,733 ($17,657); $P=0.097$ and overall medical costs (including hospitalization costs) of $6,804 ($17,107) vs. $8,664 ($21,211); $P=0.063$, and significantly higher outpatient pharmacy costs of $2,736 ($3,402) vs. $1,544 ($3,162); $P<0.001$.

CONCLUSIONS: Compared to 3 months pre-initiation, HF hospitalization was lower in the first 3 months following SAC/VAL initiation, which may have been associated with the trend toward lower medical costs. Over a short term following SAC/VAL initiation, reduced medical costs may offset the increase in outpatient pharmacy costs. Further research is needed to examine potential longer-term medical savings when using SAC/VAL over time.

SPONSORSHIP: Novartis Pharmaceuticals.

I16 Predictors of Cardiovascular Risk in Patients with Atherosclerotic Cardiovascular Disease

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BACKGROUND: Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) is the newest class of lipid lowering therapy. One indication for PCSK9i is for additional low density lipoprotein cholesterol (LDL-C) lowering in patients with atherosclerotic cardiovascular disease (ASCVD) on maximally tolerated statin therapy. Having ASCVD places a patient at high risk of having a subsequent cardiovascular (CV) event. However, some patients with ASCVD may be at an even higher risk of having a CV event.

OBJECTIVE: To identify risk factors, on top of ASCVD, which place a patient at an even higher risk for a CV event.

METHODS: This was a retrospective study of the Truven Health MarketScan Commercial Database including patients ≥18 to <65 years indexing on an LDL-C value ≥70 mg/dL with evidence of ASCVD (defined by 2013 ACC/AHA guidelines) and statin use in the year pre-index who were continuously enrolled for 730 days before and up to 730 days after index or until death. Index window was from 1/1/12 to 12/31/13. CV events (myocardial infarction, unstable angina, stroke, transient ischemic attack, and revascularization in the absence of another CV event) in the post-index period were observed. Multivariate analysis including demographic and baseline clinical characteristics was used to estimate factors that predict CV risk.

RESULTS: The study included 5,276 patients; 56.3 [SD=5.8] years, 50.6% female. In the multivariate analysis, age, diabetes (DM), chronic kidney disease (CKD), and having a CV event in the 12 months pre-index were found to be significant predictors of a CV event in the following year. With every 5 years increase in age there was an 18.5% increase in risk of CV event ($P=0.006$). In patients with a diagnosis of DM or CKD there was a 70% ($P<0.001$) and 115% increase ($P=0.036$) in risk of a CV event, and, if present together, a 301% ($P<0.001$) increase in risk. For patients with a CV event in the past year, there was a 92% increase in risk of having a CV event in the following year ($P<0.001$).

CONCLUSIONS: Certain characteristics such as age, DM, CKD, and a recent CV event increase CV risk in an already high-risk ASCVD patient population. Urgent and aggressive lipid lowering therapy must be implemented in ASCVD patients who need additional LDL-C lowering, especially in those with additional risk factors described above.

SPONSORSHIP: Amgen.

I17 Analysis of Patient Characteristics as Covariates Potentially Affecting Pharmacokinetics, Efficacy, or Safety of Betrixaban in the APEX Study

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BACKGROUND: Betrixaban (Btx) is a direct inhibitor of factor Xa (FXa) for prevention of venous thromboembolism (VTE) in at-risk patients hospitalized for acute medical illness. A phase 3 trial (APEX) compared extended prophylaxis with Btx to enoxaparin in acute medically ill patients.

OBJECTIVE: To analyze the potential effect of patient characteristics on population pharmacokinetics (PK) and exposure-response relationships for acute medically ill patients who received Btx in the APEX study.

METHODS: Patients received Btx (35-42 days; n=3,759) or enoxaparin (10±4 days; n=3,754). The primary efficacy and safety endpoints were composite occurrence of VTE events and incidence of major bleeding; secondary endpoints included incidence of clinically relevant non-major (CRNM) bleeding. Btx dose was 80 mg PO QD (40 mg for patients with severe renal insufficiency or requiring a concomitant strong P-glycoprotein [P-gp] inhibitor). PK samples were collected at hospital discharge (Day 14 after randomization); samples were taken 0-5 hours or 10-30 hours after the most recent dose of study medication. Patient characteristics included age, sex, race, region, body weight, CrCl category, and specific P-gp inhibitor.

RESULTS: In total, 3,146 PK samples from patients who received Btx were analyzed. For the 80 mg dose, the projected concentration was 18.8 ng/mL at 2 hours post-dose and 16.1 ng/mL at 20 hours post-dose, showing a stable daily concentration level on QD dosing. Co-administration of two P-gp inhibitors (amiodarone or clarithromycin) on the day of sampling more than doubled Btx concentration to ~35 ng/mL at 20 hours post-dosing. For the 40 mg dose, the projected concentration was 7.2 ng/mL at 20 hours post-dose, indicating a greater-than-dose-proportional exposure relationship. Patient age, sex, weight, CrCl category, P-gp inhibitors, and region were identified as significant covariates affecting Btx PK. The exposure-response relationship for the primary efficacy endpoint was not significant, but the relationship between Btx concentration and major or CRNM bleeding was significant in multivariate testing ($P=0.011$).

CONCLUSIONS: The Btx PK profile exhibited stable serum concentrations with QD dosing. Several covariates had a 15%-20% effect on Btx concentration, but no effect on efficacy or safety. Due to increased observed concentrations, Btx dose should be adjusted to 40 mg for patients taking amiodarone or clarithromycin, but not other P-gp inhibitors. Adjustments of Btx dose should not be necessary for patients characterized by other covariates tested in this analysis.

SPONSORSHIP: Portola Pharmaceuticals.

I18 Persistence of Droxidopa Treatment in Patients with Neurogenic Orthostatic Hypotension

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BACKGROUND: Droxidopa is approved in adults by the U.S. Food and Drug Administration for the treatment of the symptoms of neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure, dopamine beta-hydroxylase deficiency and nondiabetic autonomic

neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. Patients with nOH experience a decrease of ≥20 mmHg in systolic blood pressure (BP) or ≥10 mmHg diastolic BP within 3 minutes after standing. Symptoms of nOH are due to impaired autonomic response and include orthostatic dizziness, lightheadedness, or presyncope (i.e., the feeling of "blacking out") which place patients at greater risk of falling and severe impairment in their health-related quality of life. Droxidopa was approved based on data from 3 randomized controlled trials with treatment periods ranging from 1-8 weeks. In a long-term, open-label extension study of droxidopa (mean duration of exposure, 363 days), 17% and 12% of the study population discontinued due to adverse events and lack of efficacy, respectively. There have been no additional reports regarding the persistency of patients on droxidopa.

OBJECTIVE: To assess the persistence of droxidopa treatment in a real-world setting for patients with nOH.

METHODS: A retrospective analysis of patients who were prescribed droxidopa was performed using Symphony Health Solutions Database (Symphony Health, Conshohocken, PA). Patients who received a prescription for droxidopa and had continuous insurance coverage from September 1, 2014, to March 31, 2017 (inclusive) were included. Because access to droxidopa is highly restricted by some payers, persistency was based upon the single longest episode of care.

RESULTS: A total of 2,735 patients were included in the analysis. The mean±SD duration of treatment with droxidopa was 245.6±244.2 days, with a median duration of 150 days. There was a considerable drop-off of utilization after 30 days, with 26% of patients ending treatment. At 90 days (~3 months) and 180 days (~6 months), 64% and 47% of patients remained on droxidopa. Of those who remained on therapy at day 31, 86% and 64% remained on therapy at 90 and 180 days, respectively.

CONCLUSIONS: Overall rates of treatment persistence with droxidopa were high. The observed 26% drop-off in the number of patients on droxidopa between day 1 and day 31 is likely associated with insurance coverage issues. The persistency rate observed in this analysis is suggestive of long-term durability and tolerability of droxidopa in patients with nOH.

SPONSORSHIP: Lundbeck.

J00-J99 Diseases of the Respiratory System
(e.g., Asthma, COPD, Rhinitis, RSV)

J1 Impact of an Immunization Mail Reminder to Medicare Beneficiaries on Influenza and Pneumococcal Vaccination Rates

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BACKGROUND: Despite the known protective benefits of pneumococcal and influenza vaccination in adults over 65, U.S. influenza and pneumococcal vaccination rates in this population remain suboptimal. With healthcare emphasizing preventative, value-based care, improving vaccination rates is an opportunity for healthcare systems to reduce influenza and pneumococcal-related complications and healthcare utilization. This study evaluated the impact of an immunization mail reminder on influenza and pneumococcal vaccination rates in Medicare beneficiaries.

OBJECTIVE: To evaluate the impact of an immunization vaccine mail reminder intervention on influenza and pneumococcal immunization rates in Medicare beneficiaries.

METHODS: An immunization mail reminder was sent to over two million Medicare beneficiaries in December 2016. Medical claims were queried for pneumococcal and influenza vaccinations. The 2016-2017 intervention cohort (Y2) was compared to a 2015-2016 historical control (Y1) who did not receive a mail reminder. The change in proportion of vaccinations occurring during the intervention evaluation phase (January thru March) was compared between the two cohorts. Additional subset analyses evaluated the impact of age and Medicaid eligibility on vaccination rates.

RESULTS: Overall, pneumococcal vaccinations declined from Y1 to Y2 (7.3% vs. 5.4%, $P<0.001$) while influenza vaccinations mildly increased from Y1 to Y2 (16.6% vs. 18.4%, $P<0.001$). Of the total annual populations, the vaccination rate during the intervention evaluation period declined from Y1 to Y2 for pneumococcal vaccinations (2.1% vs. 1.5%, $P<0.001$) and increased for influenza vaccinations (0.7% vs. 0.9%, $P<0.001$). In addition, age groups 65-75 and >75 were associated with a higher likelihood of influenza vaccination (0.7% vs. 0.9%, $P<0.001$ and 0.6% vs. 0.8%, $P<0.001$, respectively) during the intervention evaluation phase.

CONCLUSIONS: The results of our study suggest that a mailed immunization reminder to Medicare beneficiaries did not have a significant impact on pneumococcal vaccination rates, but did have a significant impact on influenza immunization rates. Evaluation of alternative methods of reaching these members should be conducted to improve pneumococcal vaccination rates.

SPONSORSHIP: AMCP Foundation/Pfizer internship.

J2 Financial Burden Associated with the Use of Guideline-Concordant Therapy for the Treatment of Hospitalized Patients with Community-Acquired Bacterial Pneumonia

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BACKGROUND: The morbidity, mortality, and costs associated with the management of hospitalized adult patients with community-acquired bacterial pneumonia (CABP) are considerable. It is estimated that ~3 million U.S. patients are treated for CABP in hospitals annually, resulting in nearly $10 billion in hospital costs. Although treatment guidelines for patients with CABP exist and are followed by most institutions, a recent, real-world study suggested that up to 40% of patients who receive the most commonly prescribed guideline-concordant therapy, ceftriaxone (CTX)-azithromycin (AZI), fail to achieve clinical response by day 4, which is a clinical response endpoint endorsed by the FDA for Phase III registration CABP trials. Further, the impact of Clostridium difficile associated with CABP guideline concordant treatment on costs and outcomes has yet to be attributed.

OBJECTIVE: The objective of this study was to estimate the cost associated with the management of hospitalized CABP patients treated with CTX-AZI. As part of this analysis, we sought to determine the incremental cost among patients who achieved a clinical response by day 4 versus those failing to respond by day 4.

METHODS: An economic model from the hospital perspective was created. The patient population included those age ≥18 years who were hospitalized, met ATS/IDSA criteria for CABP with a PORT risk class III or IV,and received CTX-AZI for ≥24 hrs. In this study the median (IQR) hospital LOS for day 4 responders was 5 days (3.5-7) and 9 days (6-14) for day 4 non-responders. The incremental costs and adverse effects associated with day 4 non-responders versus day 4 responders were determined. Daily hospital costs were derived from HCUP data and probabilities and costs for *Clostridium difficile* were derived from

recent literature. Costs were adjusted to 2017 dollars. A probabilistic sensitivity analysis was conducted.

RESULTS: Average costs among day 4 non-responders were $15,383 while costs among day 4 responders were $4,830. The incremental cost associated with the management of day 4 non-responding CABP treated with CTX-AZI was $9,118 dollars. The model was sensitive to probabilities for lack of day 4 response and for Clostridium difficile infection.

CONCLUSIONS: A proportion of adult patients with CABP treated with CTX-AZI do not achieve a clinical response by day 4. The financial burden associated with a lack of clinical response by day 4 with guideline-concordant treatment of CABP is significant. Assessment of the impact of new therapies for adult CABP on patient outcomes and costs is warranted.

SPONSORSHIP: Nabriva Therapeutics.

J3 Respiratory Syncytial Virus Hospitalization Rates and Costs Among Full-Term and Preterm Infants Before and After Implementation of the 2014 American Academy of Pediatrics Guidance on Immunoprophylaxis

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BACKGROUND: The 2014 American Academy of Pediatrics (AAP) guidance on respiratory syncytial virus (RSV) immunoprophylaxis recommended against the use of palivizumab in infants 29-34 weeks gestational age (wGA) without chronic lung disease (CLD) or acyanotic congenital heart disease (CHD). Previous studies have shown an increase in RSV hospitalization (RSVH) rates among infants 29-34 wGA and < 3 months chronologic age (CA) in the first season after the guidance change (2014-15), but there is interest in disease rates over multiple seasons. Additionally, RSVH costs after that point have not been thoroughly examined.

OBJECTIVE: To compare RSVH rates during the 2014-16 RSV seasons versus the 2012-14 RSV seasons and to describe RSVH costs in the 2014-16 RSV seasons for full-term and preterm infants based on paid insurance claims.

METHODS: Infants < 1 year of age between July 1, 2012 and June 30, 2016 were selected in the MarketScan Commercial database; DRG and ICD-9-CM codes were used to identify full-term (FT; n = 604,754) and preterm infants 29-34 wGA without CLD or CHD (n = 29,525). RSVH rates between November and March of each year were evaluated, and rates were calculated per 100 infant-seasons. RSVH costs for the 2014-16 seasons were averaged separately for FT and preterm infants by age at first RSVH.

RESULTS: Compared to the 2012-14 seasons, RSVH rates among infants < 3 months CA decreased in 2014-16 by 16% for FT infants and increased by 69% for infants 29-34 wGA. Among infants 3-6 months CA, RSVH rates decreased for FT infants by 13% and increased for infants 29-34 wGA by 44%. RSVH rate increases were highest for infants 29-30 wGA < 3 months CA (263%) and 31-32 wGA < 3 months CA (101%). Absolute rates were highest for infants 29-34 wGA in the 2015-16 season relative to the other 3 seasons (5.0 per 100 for < 3 months CA and 2.8 per 100 for 3-6 months CA). The average RSVH cost for infants < 3 months CA was $17,425 for FT infants and $39,362 for infants 29-34 wGA. For infants 3-6 months CA, the average RSVH cost was $14,804 for FT infants and $21,534 for infants 29-34 wGA.

CONCLUSIONS: Multiple studies of the 2014-15 RSV season demonstrated increased rates of RSVH after the 2014 AAP guidance change, particularly among infants 29-34 wGA and < 3 months CA. This study demonstrates that a similar, if not greater, increase was observed in the 2015-16 RSV season. In addition, costs of RSV hospitalizations were shown to be substantially higher for infants 29-34 wGA and < 3 months CA compared to full-term infants.

SPONSORSHIP: AstraZeneca.

J4 Economic Impact Associated with a Reduction in Surgical Eligibility Among Newly Diagnosed Patients with Chronic Rhinosinusitis: A Managed Care Cost Offset Model

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BACKGROUND: Chronic rhinosinusitis (CRS) is a high-prevalence, chronic, and debilitating inflammatory disease generating ~$10B in direct and $20B in indirect costs per year in the U.S. Evidence suggests that current medical treatment is associated with high rates of failure and low treatment satisfaction, and that approximately 1/3 of patients progress to endoscopic sinus surgery (ESS) within 6 months of diagnosis. While some patients treated with ESS experience a significant improvement in their symptoms, it is reported that recurrence of uncontrolled CRS symptoms occurs in about half of patients, and that ESS carries a 1% risk of serious post-surgical complications such as CSF leak, vision loss and nasal atrophy. Maximal medical therapy (MMT) is recommended prior to surgery, and new medical treatments are being developed that may reduce surgical eligibility rates and costs. A model has been constructed to estimate the potential economic benefit of such improvements.

OBJECTIVE: To quantify the potential cost offsets from reduced surgical eligibility from the perspective of U.S. payers

METHODS: A three-year cost-offset model was developed incorporating CRS-related parameters derived from the medical literature: incidence, surgical progression rate, surgical revisions, post-surgical complication rate, post-surgical healthcare costs, and a sensitivity range of estimates for possible surgical eligibility reduction rates with improved MMT. Costs were adjusted to 2017 dollars. A probabilistic sensitivity analysis was conducted.

RESULTS: In a 1M member plan, approximately 22,000 new CRS patients would be identified over 3 years, 46% of whom would eventually be treated with ESS (8,996 ± 50.7 procedures). ESS, revisions, and complications would account for 69 ± 0.3% of overall CRS costs. Each 10% reduction in the surgical rate through MMT would avoid 900 ± 5.1 ESS procedures, 89 ± 1.7 revisions, and 9 ± 0.3 complicated surgeries. A total of $11.5 ± 0.2M in ESS-associated costs could be avoided, including $9.2 ± 0.1M in surgical costs, $1.08 ± 0.01M in office visits, $0.7 ± 0.02M in radiology and endoscopy costs, and $0.6 ± 0.02M in medications. Overall, the projected cost offset for each 10% reduction would be $3.84 ± 0.07 per member per year, or $172 ± 3 per patient per year. The model was most sensitive to changes in the cost of surgery, the rates of surgery over 3 years and during the first 6 months.

CONCLUSIONS: In this cost offset model, reductions in surgical eligibility achieved through medical treatment have the potential to meaningfully reduce direct costs among patients with CRS.

SPONSORSHIP: OptiNose U.S.

J5 The Adoption of Short-Acting Beta-Agonist Inhalers with Integrated Dose Counters in a Managed Care Plan: A Budget Impact Model

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BACKGROUND: Short-acting beta-agonist (SABA) inhalers with an integrated dose counter (IDC) could potentially reduce healthcare resource utilization (HRU) and cost as they allow patients to reliably track their rescue medication usage and adapt management of their disease, if needed. IDCs allow patients to determine the number of remaining doses available in their inhaler.

OBJECTIVE: To compare the economic impact of SABAs with and without an IDC when used by managed care patients with obstructive respiratory diseases (asthma, chronic obstructive pulmonary disease [COPD], exercise-induced bronchospasm [EIB]) through a budget impact model.

METHODS: The model was based on data derived from a United States (U.S.) retrospective database analysis of patients with asthma, COPD, or EIB on SABAs with and without an IDC. This included the number of SABA prescription fills per year, and HRU, including number of hospitalizations, emergency room visits and other inpatient or outpatient visits. Epidemiological data, market uptake scenarios, and drug and disease-related costs were included in the model to estimate the budget impact in a hypothetical U.S. managed care plan with 1 million members over a 3-year period. Drug costs were based on the 2016 Red Book online. Annual total costs and cost per member per month (PMPM) were considered for three scenarios that accounted for variability in the uptake of IDCs over a 3-year period. IDC uptake was assumed as: 1% (year 2) and 2% (year 3) in scenario 1 (base model), along with the low-uptake scenario 2 (rates at 50% vs. scenario 1), and high-uptake scenario 3 (200% vs. scenario 1). Sensitivity analyses were performed to determine the most influential variables in the model.

RESULTS: The use of SABAs with an IDC demonstrated a cost savings in annual total costs across all 3 scenarios. In scenario 1, total costs savings of $3,246,979 and $6,492,522 was achieved by year 2 and 3, respectively. PMPM cost savings were $0.27 in year 2 and $0.54 in year 3. Cost savings were also demonstrated in scenario 2 (low-uptake) and scenario 3 (high-uptake), with results ranging from $162,932 to $12,984,537, annually, and $0.01 to $1.08, PMPM. Cost savings were attributed to a reduction in both drug-related costs and more notably, disease-related costs and driven primarily by reduction in hospitalization costs.

CONCLUSIONS: The adoption of SABAs with an IDC in a managed care plan may result in a total annual and PMPM costs savings causing an overall decreased budget impact on total healthcare costs.

SPONSORSHIP: Teva Pharmaceuticals.

J6 Pharmacist-Initiated Albuterol Order Optimization and Education in an Adult Asthma Population

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PROBLEM DESCRIPTION: Asthma is one of the most prevalent chronic diseases, and the annual cost of care in the United States is estimated to be over $50 billion. Inadequate asthma symptom control may lead to increased utilization of emergency services and hospitalizations, both of which increase the overall cost of patient care. Nationally, health plans are assessed by a Health Effectiveness Data and Information Set (HEDIS) measure called the asthma medication ratio (AMR). The AMR compares dispensing of controller medications with that of reliever medications for each member with persistent asthma, and adequate control is represented by an AMR of at least 0.5. An increase in reliever dispensing without a similar increase in controller dispensing negatively affects the member's AMR—and subsequently the health plan's HEDIS measure—as this may indicate poorly controlled asthma.

GOAL: To improve AMR by reducing overutilization of albuterol inhalers and educating members on asthma symptom control.

PROGRAM DESCRIPTION: Between October and December 2016, a clinical pharmacist identified 234 members who met the HEDIS criteria for persistent asthma, had an AMR of less than 0.5, and had a current albuterol prescription order with at least two canisters remaining for refill. The pharmacist converted each prescription order to one canister with zero refills and sent the new order to the physician for approval through the electronic medical record system. Once the new order was approved, members were notified of the prescription change and educated on clinical symptoms that may indicate the need to step up therapy. Additionally, members were instructed to follow up with the physician should they need more refills of albuterol. Two hundred three of the 234 members identified received the intervention.

OBSERVATIONS: As of July 2017, of the 203 members who received the intervention, 26 members had disenrolled, and 23 members no longer met criteria for inclusion in the AMR measure, leaving 154 available for follow up. The average AMR in this group increased from 0.22 to 0.37. Controller dispensing in this group also increased, and 51 members (33%) now have an AMR of at least 0.5.

FINDINGS/RECOMMENDATIONS: This pharmacist-driven intervention improved member AMR scores over a short time. Increased controller dispensing was an indirect outcome of the intervention. Given the higher cost of controllers relative to relievers, this finding suggests that lack of education was the barrier to appropriate asthma management for some members. Education is a valuable intervention to improve symptom control and support positive clinical outcomes for members with asthma.

SPONSORSHIP: None.

J7 Spirometry Evaluation to Assess Performance of a Claims-Based Predictive Model to Identify Patients Likely to Have Undiagnosed Chronic Obstructive Pulmonary Disease

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BACKGROUND: A claims-based model to predict patients likely to have undiagnosed chronic obstructive pulmonary disease (COPD) was previously developed by Moretz et al. This study evaluates the performance of this claims-based predictive model using prospectively collected spirometry data.

OBJECTIVE: To assess performance of a claims-based predictive model to identify patients likely to have undiagnosed COPD using spirometry data.

METHODS: A study population aged 40-89 years, enrolled in a Medicare Advantage plan with Prescription Drug coverage (MAPD) or a commercial health plan, with ≥2 years of continuous enrollment and without a claim for COPD diagnosis, was identified during 4/1/2012 to 3/31/2016 in the Humana claims database. This population was then stratified into subjects likely or unlikely to have undiagnosed COPD using the claims-based predictive model. Subjects living within 20 miles of three Humana Guidance Centers (Knoxville, TN; Tamarac, FL; and Tampa, FL) were randomly invited for spirometry evaluation. Forced expiratory volume in 1 second (FEV1) and forced vital capacity

(FVC) were recorded. The model validation was based on airflow limitation ratio (FEV1/FVC < 70%) as measured with spirometer, against the COPD status (likely or unlikely to have undiagnosed COPD) from the claims-based predictive model. The following performance measures were assessed: area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

RESULTS: There were 3,213 likely and 3,774 not likely to have undiagnosed COPD subjects around the three guidance centers invited for spirometry evaluation. Of these, 218 subjects likely and 331 not likely to have undiagnosed COPD completed spirometry evaluation. Subjects predicted to have undiagnosed COPD had a higher mean age (70.2 vs. 67.9 years, $P = 0.0012$) and a lower mean FEV1/FVC ratio (72.4 vs. 75.3, $P = 0.0002$) compared to those predicted not to have undiagnosed COPD. Based on spirometry evaluation of the claims-based model, performance parameters were as follows: AUC = 0.61, sensitivity = 52.5%, specificity = 64.6%, PPV = 33.5% and NPV = 80.1%.

CONCLUSIONS: This evaluation suggests that the claims based predictive model identifies those not at risk eight out of ten times, and identifies those who may need evaluation to further confirm their COPD diagnosis one out of three times. Early diagnosis of COPD may help in better management of the disease and may help prevent exacerbations.

SPONSORSHIP: Boehringer Ingelheim and Humana.

J8 Assessment in a Real-World Setting of the Effect of Inhaled Steroid-Based Triple Therapy Versus the Combination of Tiotropium and Olodaterol on Reducing Chronic Obstructive Pulmonary Disease Exacerbations: AIRWISE Study Design

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PROBLEM DESCRIPTION: The role of the triple therapy combination of a long-acting muscarinic antagonist (LAMA), a long-acting β2-agonist (LABA), and an inhaled corticosteroid (ICS) in chronic obstructive pulmonary disease (COPD) is a topic of debate. The Global initiative for chronic Obstructive Lung Disease (GOLD) 2017 recommends step-up from LAMA/LABA to triple therapy if patients have further exacerbations. However, GOLD acknowledges more evidence is needed to draw conclusions on the benefits of triple therapy versus LAMA/LABA. In addition, payers and clinicians seek real-world evidence for the pharmacologic treatment of COPD.

GOAL: To generate scientifically rigorous evidence in a real-world setting to guide clinical and budgetary decision-making by comparing clinical and health-care resource utilization (HCRU) outcomes of patients with COPD, randomized to the fixed-dose combination of tiotropium and olodaterol (T/O) or triple therapy.

PROGRAM DESCRIPTION: This 12-month, randomized, open-label, pragmatic clinical trial (PCT) will enroll 3200 patients across 400 community-based physician sites. Reflecting the pragmatic design, patients will be randomized to T/O or triple therapy (1:1 ratio) following the physician's decision to escalate therapy. The minimal inclusion criteria are age ≥40 years with COPD deemed by the physician to be not controlled on current therapy (LAMA or LABA, or ICS/LABA). Other than collection of baseline measures, patients will receive usual care and be followed for 12 months with both site-level and claims data collected. The study is due to begin enrolling in Q3 2017.

OBSERVATIONS: Primary endpoint is time to first moderate or severe COPD exacerbation. Secondary endpoints include annual rate of moderate or severe exacerbations, time to first and annual rate of severe exacerbations, and proportion of patients with moderate or severe exacerbations. Safety, all-cause and COPD-related HCRU and costs, and the main drivers of HCRU, will also be evaluated. The primary endpoint will be analyzed on site-level data using a Cox proportional hazards model. A sensitivity analysis will be performed for the primary endpoint by integrating site-level and claims data.

FINDINGS/RECOMMENDATIONS: The AIRWISE study is the first large-scale U.S. PCT in COPD. The research question and endpoints directly address a pivotal clinical question put forward by GOLD 2017 and will provide much-needed real-world clinical and HCRU evidence for clinicians, payers, and health policy makers.

SPONSORSHIP: Boehringer Ingelheim.

J9 Health-Care Resource Utilization, Costs, and Exacerbation Rates in Patients with COPD Stratified by GOLD Airflow Limitation Classification in a U.S. Commercially Insured Population

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterized by increasing airflow obstruction and is a major cause of morbidity, mortality, and health-care burden. Data are limited on how health-care resource utilization (HCRU) and cost of care relate to COPD severity.

OBJECTIVE: To evaluate HCRU, cost of care, and exacerbation rates in COPD patients classified into four stages of COPD severity (based on forced expiratory volume in 1 second) according to Global initiative for chronic obstructive lung disease (GOLD).

METHODS: Newly diagnosed COPD patients were identified from the HealthCore Integrated Research Database from Jan 2012-Nov 2013. Inclusion criteria were ≥ 1 inpatient/ER claim or ≥ 1 outpatient claim with diagnosis of COPD, age ≥ 40 years, and continuous health plan enrollment ≥ 12 months before and ≥ 24 months after COPD diagnosis. Medical records were obtained for a sample of patients with ≥ 1 claim for spirometry to confirm COPD diagnosis and determine GOLD classification 1-4 (mild-very severe). All-cause and COPD-related HCRU and costs were calculated, along with the rate of moderate/severe exacerbations requiring oral corticosteroid/antibiotic, ER visit, or hospitalization.

RESULTS: Of 1,505 patients with spirometry-confirmed COPD, 333 (22%), 823 (55%), 317 (21%), and 32 (2%) were classified as GOLD 1-4, respectively. All-cause ER visits and inpatient admissions were highest in GOLD 4 patients, with ≥ 1 ER visit in 40, 37, 36, and 44% and ≥ 1 inpatient admission in 38, 44, 47, and 75% of GOLD 1-4 patients, respectively. All patients had ≥ 1 all-cause office visit (mean: 13, 12.6, 11.6, 11.4 for GOLD 1-4). COPD-related HCRU increased with COPD severity for GOLD 1-4: 11, 14, 18, and 31% of patients had ≥ 1 ER visit; 23, 30, 40, and 72% had ≥ 1 inpatient admission; and mean office visits were 1.9, 2.5, 3.6, and 4. Annual all-cause total health-care costs were greatest in GOLD 4 patients ($31,148) but similar for GOLD 1-3 patients ($22,217, $21,594, $22,520). Annual COPD-related total health-care costs increased with COPD severity ($5,945, $6,978, $10,751, $18,070 for GOLD 1-4). Rate of moderate/severe exacerbations also increased with GOLD 1-4: 40.4, 48.9, 83.6, and 89.1 exacerbations/100 patient-years, respectively.

CONCLUSIONS: In a real-world study of newly diagnosed patients with COPD, the frequency of COPD-related HCRU, moderate/severe exacerbation rates, and COPD-related total health-care costs increased with COPD severity, GOLD stage 1-4.

SPONSORSHIP: Boehringer Ingelheim.

J10 Association of Elevated Peripheral Blood Eosinophil Counts and Resource Use in Patients with Asthma

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BACKGROUND: There is little agreement on a clinically meaningful definition of eosinophil (EOS) elevation, with neither widely accepted absolute blood count threshold nor range of values that have been determined to influence patient outcomes and cost.

OBJECTIVE: This study sought to assess the impact of blood EOS elevation by correlating laboratory results with resource use in real-world setting.

METHODS: We compared differences in resource use (hospitalizations, ER visits, and outpatient visits) among asthma patients with and without blood EOS elevation defined separately at thresholds ≥150 cells/μL and ≥300 cells/μL. Data on patients 18 years or older with asthma (ICD-9 493.xx or ICD-10 J45) were extracted from a Midwest-focused health system component of EMRClaims+, which included an overlap of patient EMR data with insurance claims (2012-2016). Patients were required to have been continuously enrolled for 12 months after asthma diagnosis (assessment period) and 12 months after the assessment period, defined as the follow-up period. Patients were flagged for elevated blood EOS if at least one test showed the presence of ≥150 cells/μL, and as part of a separate analysis, ≥300 cells/μL, within 3 months prior to follow-up. Logistic regression assessed the probability of hospitalization with EOS elevation serving as a potential predictor among other covariates such as demographics and comorbidities.

RESULTS: The study included 2,321 patients of whom 466 (20%) and 249 (11%) had elevated EOS at ≥150 cells/μL and ≥300 cells/μL, respectively. Percentages of patients with a hospitalization (any cause) during the follow-up period were significantly greater in the elevated group (at ≥150 cells/μL: 18% vs. 10%, $P<0.0001$; at ≥300 cells/μL: 18% vs. 11%, $P=0.0004$). Similarly, a greater percentage of patients had office visits in the elevated group (at ≥150 cells/μL: 65% vs. 52%, $P<0.0001$; at ≥300 cells/μL: 62% vs. 53%, $P=0.011$). A greater percentage (but not statistically significant for ≥300 cells) of patients with elevated EOS had ER visits as well (at ≥150 cells/μL: 38% vs. 29%, $P=0.0004$; at ≥300 cells/μL: 35% vs. 30%, $P=0.097$). Those with EOS elevation had 62-66% greater likelihood of being hospitalized during follow-up (at ≥150 cells/μL: OR: 1.658; 95% CI: 1.236-2.224; at ≥300 cells/μL: OR: 1.616; 95% CI: 1.121-2.332).

CONCLUSIONS: Eosinophil elevations of ≥150 cells/μL and ≥300 cells/μL were associated with higher resource use and increased likelihood of hospitalization during follow-up.

SPONSORSHIP: AstraZeneca.

J12 Relationship Between Performance on the Medication Management for Asthma Quality Measure and Asthma-Related Physician Office Visits and Emergency Department Visits: Implications for Quality Improvement Strategies

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BACKGROUND: Adherence to asthma long-term controller medications (LTCMs) helps to prevent asthma exacerbations that can result in expensive emergency department (ED) visits. Adherence to LTCMs was included in the HEDIS Medication Management of Asthma (MMA) quality measure and the Medicaid Child Core Set. The Mississippi Medicaid drug utilization review program uses this measure to assess quality in both fee-for-service and managed care plans.

OBJECTIVE: To evaluate relationships between performance on the MMA quality measure and asthma-related physician office (PO) visits and ED visits among children in Mississippi Medicaid.

METHODS: A retrospective observational study used Mississippi Medicaid claims data to calculate performance for calendar year 2016 according to the HEDIS criteria. Included were children 5-20 years of age, continuously enrolled and diagnosed with persistent asthma. Excluded were children diagnosed with other respiratory conditions, admitted to long-term care or dually eligible. The proportion of days covered (PDC) for LTCMs was calculated using the two HEDIS criteria—PDC≥75% and PDC≥50%. The adjusted relative risks of asthma-related ED visits and PO visits were computed for the 75% and 50% PDC levels using modified Poisson regression.

RESULTS: A total of 7,661 children met the criteria for the MMA measure. Of these, 73.6% were non-adherent using PDC≥75% and 49.9% were non-adherent using PDC≥50%. Compared to adherent patients, the adjusted relative risk of asthma-related ED visits for children non-adherent using PDC≥75% was 1.26 (95% confidence interval [CI]: 1.10-1.44) and when using PDC≥50% was 1.17 (CI: 1.05-1.30). The adjusted relative risk of asthma-related PO visits for children non-adherent using PDC≥75% was 0.87 (CI: 0.84-0.90) and when using PDC≥50% 0.88 (CI: 0.86-0.91).

CONCLUSIONS: A substantial percentage of children with asthma had low adherence with LTCMs. Non-adherent children had a higher risk of asthma-related ED visits and lower risk of asthma-related PO visits. The increased risk of ED visits demonstrates the potential cost savings possible from improved adherence. The relationships with asthma-related PO visits can be interpreted two ways. Physician visits can improve adherence or adherence behaviors for medications and PO visits are highly correlated. Since non-adherent patients are not visiting pharmacies or physicians regularly, educational interventions aimed at providers may not be effective at improving quality. Case management with non-adherent patients may be a more effective strategy.

SPONSORSHIP: None.

K00-K93 Diseases of the Digestive System
(e.g., Crohn's Disease, IBD, IBS)

K1 Retrospective Claims Study Comparing Medical Expenditure and Healthcare Resource Utilization Trends in Ulcerative Colitis Between Vedolizumab and Adalimumab Initiators

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BACKGROUND: After considering therapeutic efficacy and risk/benefit profiles, health care providers often need to consider a choice of biologic therapy such as vedolizumab (VDZ) or adalimumab (ADA) for patients (pts) with moderate to severe ulcerative colitis (UC). Although biologics may have similar efficacy, they may differ in their mechanism of action and thus side effect and safety profiles.

OBJECTIVE: This retrospective claims analysis compared real-world UC-related medical costs and healthcare resource utilization (HRU) rates for hospitalizations, emergency department visits, surgeries, office visits, endoscopies, scans, and laboratory testing (costs only) for biologic-naive and biologic-experienced pts initiating VDZ or ADA therapy.

METHODS: UC pts (≥18 years old) initiating therapy on VDZ or ADA were identified using medical and pharmacy administrative claims from the Truven Marketscan database from 1/1/2015 to 03/31/2016. Pts were required to have ≥6 months pre-/post-index continuous enrollment and no prior use of the index drug. Generalized linear models were used to fit annualized changes in medical costs (follow-up minus baseline) assuming a gamma distribution and a log link, and HRU event rates per 100 patient-years assuming a Poisson distribution and a log link with an offset of log time. Statistical significance was evaluated with the Holm method.

RESULTS: Of the 860 pts (n=393 VDZ; n=467 ADA) identified, 284 VDZ pts (72%) were biologic-experienced vs. 73 ADA pts (16%). VDZ pts had a higher Quan-Charlson Comorbidity Index and less 5-aminosalicylate use but higher immunomodulator and IV steroid use at baseline. Annualized costs for VDZ vs. ADA were not significantly different for both biologic-naive and experienced pts except for scans in biologic-naive pts, which were on average significantly lower by $44 ($P<0.0001$) for VDZ after adjusting for covariates. Costs and HRU rates during follow-up vs. baseline were lower for both ADA and VDZ in biologic-naive and experienced pts; no significant differences in the rates for any of the events assessed were found between VDZ and ADA.

CONCLUSIONS: In this claims database analysis, VDZ pts had more comorbidities, had higher use of IV steroids at baseline, and were more likely biologic-experienced than ADA pts. HRU and costs post treatment initiation were generally similar for VDZ vs. ADA regardless of prior biologic use; thus, treatment considerations should also account for safety and overall risk/benefit profile of therapies.

SPONSORSHIP: Takeda Pharmaceuticals USA.

K2 Evidence of Inadequate Symptom Control and Associated Resource Use and Costs Among Patients Initiating Rifaximin Treatment for Irritable Bowel Syndrome with Diarrhea

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BACKGROUND: Irritable bowel syndrome with diarrhea (IBS-D) is a chronic gastrointestinal (GI) disorder with cardinal symptoms of abdominal pain and diarrhea. Treatment includes lifestyle/diet modifications and use of over-the-counter and prescription medications, many associated with low efficacy and poor tolerability, leading to treatment switching, discontinuation, or use of concomitant therapies.

OBJECTIVE: To describe treatment patterns and indicators of inadequate symptom control (ISC) among U.S. insured patients (pts) initiating rifaximin for IBS-D and to estimate incremental costs associated with ISC.

METHODS: Pts aged ≥18 years with ≥1 prescription claim for rifaximin 550 mg (first fill is index) from July 2011 to June 2015, with no claims for hepatic encephalopathy or traveler's diarrhea during 6 months pre- and 12 months post-index, were identified from the Truven Health MarketScan database. Treatment patterns, ISC indicators, healthcare resource use, and healthcare costs were assessed during the post-index period. ISC was defined as: (1) switch to or addition of another IBS-D treatment; (2) IBS- or diarrhea-related hospital or emergency department (ED) admission; (3) diagnosis of a condition indicating treatment failure; (4) IBS-D-related medical procedure; (5) use of a more aggressive prescription while on treatment within 140 days of prescription start; or (6) rifaximin re-treatment at any time. Generalized linear models with recycled predictions estimated incremental ISC costs, controlling for demographics, insurance type, Charlson Comorbidity Index score, and 14 general and 11 GI-related comorbidities.

RESULTS: Of 5,735 pts, 75.6% had evidence of ISC while on rifaximin. Of these, 21.8% received re-treatment with rifaximin and 34.9% received another IBS-D-related prescription. Among rifaximin re-treated pts (n=945), 74%, 16%, and 10% received 2, 3, and ≥4 courses of therapy, respectively; the proportion of pts with ISC increased with further courses of therapy (range: 67-90% for 2 to ≥4 courses). Re-treated pts with ISC had significantly more GI- and IBS-D-related hospitalizations, ED visits, physician office visits, and laboratory and other outpatient service use compared to pts without ISC (all $P<0.05$). After adjusting for demographics and comorbidities, incremental total annual GI- and IBS-D-related healthcare costs associated with ISC and subsequent re-treatment were $2,323 and $1,902, respectively (both $P<0.001$).

CONCLUSIONS: ISC among pts initiating rifaximin therapy was associated with significant increases in resource use and costs, representing a substantial burden for payers and IBS-D pts.

SPONSORSHIP: Allergan.

K3 Plecanatide Significantly Improved Health-Related Quality of Life in Two Randomized Clinical Trials of Patients with Chronic Idiopathic Constipation

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BACKGROUND: Patients suffering with chronic idiopathic constipation (CIC) often report significant impairments in health-related quality of life (HRQOL). Plecanatide is an analog of uroguanylin, which activates guanylate cyclase-C receptors in the small intestine in a pH-sensitive manner to induce fluid secretion, contributing to normal bowel function. Two large-scale, randomized, double-blind, placebo-controlled, phase III studies evaluating the efficacy and safety of plecanatide in adult patients with CIC have been completed (Study-00, NCT01982240; Study-03, NCT0212247). Plecanatide is approved in the U.S. to treat adult patients with CIC.

OBJECTIVE: To evaluate the impact of plecanatide on HRQOL in adult CIC patients, as assessed by improvements in Patient Assessment of Constipation–Quality of Life (PAC-QOL) and Patient Assessment of Constipation–Symptoms (PAC-SYM) questionnaires.

METHODS: Patients with CIC (modified Rome III criteria) were randomized to plecanatide 3 mg, plecanatide 6 mg, or placebo (PBO), for 12 weeks (combined intention-to-treat population of 2,683 patients: plecanatide 3 mg, N=896; plecanatide 6 mg, N=890; PBO, N=897). HRQOL was evaluated by least squares mean changes from baseline in PAC-QOL and PAC-SYM scores (ranged 0-4, with lower scores indicating better HRQOL).

RESULTS: In both studies, HRQOL was significantly improved as early as week 4 for patients who received plecanatide 3 mg or 6 mg, as evidenced by improvement in PAC-QOL and PAC-SYM total scores and domain scores vs. PBO. At week 12, improvements in PAC-QOL were demonstrated for plecanatide 3 mg (difference from PBO [Δ] −0.25; $P<0.001$; Δ −0.20; $P<0.001$) and plecanatide 6 mg (Δ −0.28, $P<0.001$; Δ −0.19, $P<0.001$) for Study-00 and Study-03, respectively. Significant improvements in PAC-SYM scores at week 12 compared to PBO were demonstrated for plecanatide 3 mg (Δ −0.22; $P<0.001$; Δ −0.18; $P=0.002$) and plecanatide 6 mg (Δ −0.23, $P<0.001$; Δ −0.15, $P=0.009$) for Studies -00 and -03, respectively. Both doses of plecanatide also significantly improved the PAC-SYM domain scores of rectal and stool symptoms in both studies, and the PAC-QOL domain scores of physical discomfort, worries/concerns, and satisfaction related to bowel habits.

CONCLUSIONS: Adult CIC patients who received plecanatide reported significant improvements in HRQOL (measured by PAC-QOL and PAC-SYM) as early as the first study visit (week 4), which were maintained at all time points through week 12. Plecanatide offers the potential to improve HRQOL in patients with CIC.

SPONSORSHIP: Synergy Pharmaceuticals.

K4 Real-World Utilization of Biosimilar and Originator Infliximab in a Cohort of Patients with Inflammatory Bowel Disease in Turkey

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BACKGROUND: Little data exists about real-world use of biologic medications and their biosimilar preparations to treat inflammatory bowel disease.

OBJECTIVE: This study evaluated real-world prescribing and utilization patterns for originator infliximab (IFX) or biosimilar infliximab (CT-P13) in Turkey. The data from this country could be unique in revealing insights into utilization because there is minimal cost difference that exists between the two medications in Turkey.

METHODS: The Turkish Ministry of Health Database was used to identify patients with ≥1 claim with diagnosis of ulcerative colitis (UC) or Crohn's disease (CD) and an IFX or CT-P13 claim; no prior use of medication for ≥12 months before IFX or CT-P13 initiation (index date). Patients were >18 yrs of age, had ≥6 months follow-up post-index date. The proportion receiving IFX or CT-P13, and utilization patterns were studied. A confirmed discontinuation was defined as a switch to another biologic or ≥120-day gap in claims for the index biologic.

RESULTS: 581 IFX-naive IBD patients met the study criteria. The majority (87%) initiated IFX. Mean age was lower in the IFX group (38 vs. 41 years; $P<0.05$). The gender distribution was similar. The proportion with a UC diagnosis was similar (55.6% IFX vs. 59.7% CT-P13; $P=0.49$). The CT-P13 group had fewer CD patients (66.5% IFX vs. 53.2% CT-P13; $P<0.0001$). In the 12 months prior to index date, baseline medication exposures such as 5-aminosalicylates, corticosteroids, and adalimumab were similar (all $P>0.05$). The IFX group had more infusions in the 6 months of follow up (mean number of infusions = 4.1 vs. 2.8; $P<0.001$) and used fewer vials per infusion (mean number of vials = 4.2 vs. 6.1; $P<0.0001$). During the 6-month follow-up, discontinuation was observed in 13.9% of IFX vs. in 48.0% of CT-P13 patients ($P<0.0001$). Mean time to discontinuation among those with a confirmed discontinuation was 79 days for IFX vs. 46 days for CT-P13 ($P<0.001$). Switching was observed more frequently in the CT-P13 group (proportion of patients switching = 8.7% IFX vs. 40.3% CT-P13; $P<0.0001$). A switch from IFX to CT-P13 was observed in 22/44 (50%) of IFX-switchers, constituting 4.4% of IFX-initiators. Switching from CT-P13 to IFX was observed in 27/31 (87%) of CT-P13-switchers, constituting 35.1% of CT-P13-initiators.

CONCLUSIONS: This study demonstrates marked differences in IFX and CT-P13 dosing, discontinuation and switching in IBD patients in Turkey. Further research to explore the reasons for these findings are needed.

SPONSORSHIP: Janssen Scientific Affairs.

K5 Plecanatide for Treating Chronic Idiopathic Constipation: A Pooled Analysis of Efficacy and Safety

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BACKGROUND: Patients with chronic idiopathic constipation (CIC) suffer from infrequent or difficult stool passage and often report accompanying abdominal symptoms, such as bloating and discomfort. Plecanatide, with the exception of a single amino acid substitution, is structurally identical to human uroguanylin, an intestinal peptide that induces fluid and ion secretion. Two 12-week, randomized, double-blind phase 3 clinical trials of plecanatide in adults with CIC have been completed (NCT01982240; NCT02122471). Plecanatide is approved in the United States for the treatment of CIC in adult patients.

OBJECTIVE: To evaluate the efficacy and safety of plecanatide in CIC in two identically designed phase 3 trials, including the impact on patient-reported secondary outcomes.

METHODS: Patients (aged 18-85 yrs) meeting modified Rome III criteria for CIC were eligible to participate and were randomized (1:1:1) to plecanatide (3 mg or 6 mg) or placebo (PBO) for 12 weeks. The primary endpoint was the percentage of durable overall complete spontaneous bowel movement (CSBM) responders. Secondary endpoints included the mean change from baseline (Δ) in the frequency of CSBMs and spontaneous bowel movements (SBMs) and the assessment of patient-reported symptoms of straining, abdominal bloating, and abdominal discomfort. Efficacy and safety data from these two 12-week trials were pooled.

RESULTS: The combined efficacy population included 2,683 patients (3 mg, N = 896; 6 mg, N = 890; PBO, N = 897). Significantly more patients treated with plecanatide were durable overall CSBM responders over 12 weeks of treatment (3 mg, 20.5%; 6 mg, 19.8%; PBO, 11.5%; $P<0.001$ vs. PBO both doses). A significantly greater change in CSBM frequency was demonstrated for plecanatide (3 mg, Δ = 1.07; 6 mg, 0.89; $P<0.001$ vs. PBO both doses) as well as SBM frequency (3 mg, Δ = 1.51; 6 mg, 1.58; $P<0.001$ vs. PBO both doses). Significant reductions in patient-reported outcomes were observed favoring plecanatide vs. PBO, including straining (3 mg, Δ = −0.31; 6 mg, Δ = −0.27; $P<0.001$ vs. PBO both doses), abdominal bloating (3 mg, Δ = −0.12; $P<0.001$ vs. PBO; 6 mg, Δ = −0.08; $P=0.009$ vs. PBO), and abdominal discomfort (3 mg, Δ = −0.11; $P<0.001$ vs. PBO; 6 mg, Δ = −0.07; $P=0.027$ vs. PBO). Both plecanatide doses were safe and well tolerated, with a low incidence of diarrhea and other side effects.

CONCLUSIONS: Plecanatide is efficacious and safe in CIC. Plecanatide 3 mg and 6 mg demonstrated improvements in clinical outcomes for patients with CIC compared to PBO and decreased the severity of straining and abdominal symptoms.

SPONSORSHIP: Synergy Pharmaceuticals.

K6 Inpatient Mortality, Payer Status, and Length of Inpatient Stay for U.S. Liver Transplant Recipients with Primary Biliary Cholangitis: Data from the Scientific Registry of Transplant Recipients

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BACKGROUND: Primary biliary cholangitis (PBC) is an important cause of chronic liver disease that can lead to advanced cirrhosis requiring liver transplant

OBJECTIVE: We assessed the prevalence, mortality, length of inpatient stay (LoS) and payer status of LT recipients with PBC in the U.S.

METHODS: From the Scientific Registry of Transplant Recipients (SRTR) data, we selected adult LT recipients with PBC. Associations of clinico-demographic data with LoS and inpatient mortality were determined.

RESULTS: Of 118,824 adult LTs in the U.S. (1994-2016), 4,878 (4.1%) had PBC without hepatocellular carcinoma: 55.3±9.4 years old, 84.4% female, 78.8% Caucasian, model for end stage liver disease (MELD) score 22.50±9.29, 66.4% with private insurance and 32.9% with public insurance (Medicare: 21.4%, Medicaid: 9.6% and other: 1.9%). Patients with public insurance were older (57.9±10.4 vs. 54.1±8.5), less college-educated (16.8% vs. 28.7%), and less actively employed (4.4% vs. 22.0%), and had more comorbidities, severe liver disease (MELD 23.3±9.5 vs. 22.0±9.2) and pre-LT life support use (8.6% vs. 6.1%) than PBC patients with private insurance (all $P<0.05$). Between 1994-2016, a significant decline was seen in private insurance coverage among PBC-LT recipients (highest 74.3% in 2004 vs. lowest 53.3% in 2014) accompanied by an increase in Medicare (15.3% in 1997 vs. 32.7% in 2013; $P<0.0001$) but not in Medicaid coverage ($P=0.15$). Over time, post-LT LoS decreased from the longest, 23.3 days in 1994, to the shortest, 14.7 days in 2007 ($P<0.0001$). Post-LT inpatient mortality fell from the highest, 12.2% in 1995, to the lowest, 3.3% in 2009 ($P=0.0003$). Multivariate analysis showed that older age (aHR=1.029 [1.013-1.046] per year), being re-transplanted (aHR=3.68 [2.53-5.36]), and being on life support (aHR=2.92 [1.76-4.86]) were associated with higher risk of mortality, while later calendar year was associated with lower risk of mortality (adjusted hazard ratio [aHR]=0.963 [95% CI: 0.943-0.983] per year (all $P<0.0004$), but type of insurance did not predict mortality ($P>0.10$). Further, earlier calendar year (beta=-0.20±0.06 days/year), older age (beta=0.22±0.04 days/year), having Medicaid (beta=2.88±1.23 days), having prior LT (beta=3.22±1.50 days/year), requiring life support (beta=11.6±1.7 days), requiring intensive care unit stay (beta=6.9±1.3 days), and inpatient death (beta=9.7±1.7 days) were independently associated with longer LoS in PBC-LT recipients (all $P<0.05$).

CONCLUSIONS: Inpatient mortality and LoS in PBC-LT recipients have decreased over the recent two decades. Having Medicaid is independently associated with longer LoS.

SPONSORSHIP: Intercept Pharmaceuticals.

L00-L99 Diseases of the Skin and Subcutaneous Tissue *(e.g., Psoriasis, Pressure Ulcers)*

L1 Potential Cost-Saving Opportunities with Early Use of Omadacycline in Hospitalized Patients with ABSSSI with Inadequate Early Response to Vancomycin Plus Piperacillin-Tazobactam: Findings from a Decision-Analytic Budget Impact Model

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BACKGROUND: Recent real-world evidence analysis suggests up to 28% of ABSSSI patients receiving vancomycin (VAN) containing regimens (including VAN plus piperacillin-tazobactam [TZP]) do not respond by day 3. Despite an inadequate early (3 day) response, these patients are typically maintained on VAN plus TZP resulting in prolonged hospital stays. Omadacycline (OMC) a once-daily antibiotic with broad spectrum activity, including MRSA, is currently under development for IV and oral treatment of patients with ABSSSI. Antibiotics with IV and oral bioequivalent formulations have been shown to shorten hospital stay across several disease states, including ABSSSI.

OBJECTIVE: The analysis explored the management of hospitalized patients with ABSSSI who have an inadequate early response to VAN. We compared maintaining these patients on VAN plus TZP vs. early switch at day 4 to OMC. As studies have shown that antibiotics with IV and oral bioequivalent formulation can safely and effectively reduce LOS, we sought to determine the economic impact of 1 and 2-day reductions in hospital LOS with OMC relative to continuing VAN plus TZP.

METHODS: An economic model was developed using a hospital perspective to estimate the budget impact of replacing the current strategy of continued VAN plus TZP with OMC for the treatment of 100 hospitalized patients who had an inadequate early VAN plus TZP response. Costs include room and board, drug acquisition, and VAN assay (on alternate days). Cost inputs: room and board ($1,359/day); VAN plus TZP acquisition ($29.40/day (WAC)); VAN trough assay ($18.46/assay); OMC acquisition cost was varied between $150 and $600/day. Two scenarios with varied differences in hospital LOS (1 to 2 days) were considered. The assumption was that the IV and oral options with OMC has the potential to reduce hospital LOS and VAN monitoring cost.

RESULTS: The incremental cost for a one day stay reduction was cost saving with OMC when the acquisition cost of OMC was <$450/day. With a two day LOS reduction, the incremental savings ranged between $244,957 and $109,957 per 100 patients treated, depending on OMC acquisition cost ($600/day to $150/day).

CONCLUSIONS: Early, targeted use of OMC has the potential to reduce the economic burden associated with hospitalized ABSSSI patients who have an inadequate early response to VAN plus TZP if it can, on average, reduce LOS among these patients by one to two days.

SPONSORSHIP: Paratek Pharmaceuticals.

L2 Healthcare Resource Utilization and Costs Among Psoriasis Patients Treated with Biologics, Overall and by Disease Severity

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BACKGROUND: Use of biologics has improved outcomes in patients with moderate-to-severe psoriasis (PsO) resulting in higher clearance, acceptable safety profiles, and better health-related quality of life. However, the costs associated with such benefits are high and to date there has been no description of health care resource utilization (HCRU) and costs among biologic-treated PsO patients stratified by disease severity.

OBJECTIVE: Describe HCRU and costs among PsO patients treated with biologics, overall and by disease severity.

METHODS: A retrospective study of adult PsO patients, de-identified in accordance with HIPAA, using QuintilesIMS PharMetrics Plus data linked to Modernizing Medicine Dermatology EMR between 1/1/2010-12/31/2015. Index date was date of first biologic claim with 90 and 360 days of continuous enrollment prior to and after index (corresponding to baseline and follow-up periods), respectively. Disease severity was based on first noted physician global assessment, body surface area, or patient global assessment during the follow-up period. Outpatient, emergency department, inpatient, and pharmacy HCRU and costs were reported. PsO-related HCRU and costs were defined as any claim associated with a diagnosis or medication for PsO.

RESULTS: There were 2,130 biologic-treated patients: 282 (13%) had mild, 116 (5%) moderate, and 49 (2%) severe PsO; 1,683 (79%) were unable to be classified. All-cause and PsO-related pharmacy costs represented 88% of all-cause total costs and 98% of PsO-related total costs for the overall cohort, respectively. 94% of all-cause pharmacy costs were PsO-related. Patients with severe or moderate disease vs. mild had higher all-cause total costs ($49.3k [severe], $42.3k [moderate], $37.7k [mild]); higher PsO-related total costs ($40.5k [severe], $34.9k [moderate], $32.7k [mild]); higher all-cause pharmacy costs ($36.4k [severe], $36.5k [moderate], $33.9k [mild]); higher PsO-related pharmacy costs ($35.6k [severe], $33.9k [moderate], $32.2k [mild]); more all-cause outpatient encounters (36 [severe], 32 [moderate], 28 [mild]); and a higher proportion of overall medications that were PsO-related (46% [severe], 42% [moderate], 34% [mild]).

CONCLUSIONS: Biologic-treated patients with moderate-to-severe PsO appear to be the most costly to the healthcare system, driven by higher pharmacy costs and more outpatient encounters when compared to biologic-treated patients with mild PsO. Improvement in PsO through newer biologic treatment options may have the potential to reduce the economic burden of PsO on the U.S. healthcare system.

SPONSORSHIP: Eli Lilly.

L3 Adherence and Persistence to Biologics Among Psoriasis Patients, Overall and by Disease Severity

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BACKGROUND: There is limited information on adherence and persistence to biologics stratified by disease severity among patients with psoriasis (PsO).

OBJECTIVE: Describe adherence and persistence to biologics among PsO patients, overall and by disease severity.

METHODS: A retrospective study of adult PsO patients, de-identified in accordance with HIPAA, using QuintilesIMS PharMetrics Plus data linked to Modernizing Medicine Dermatology EMR between 1/1/2010-12/31/2015. Index date was date of first biologic claim with 90 and 360 days of continuous enrollment prior to and after index (corresponding to the baseline and follow-up periods), respectively. Disease severity was based on first recorded physician global assessment, body surface area, or patient global assessment during the follow-up period. Adherence was measured by medication possession ratio (MPR) and proportion of days covered (PDC). MPR was defined as the number of days supplied during the follow-up period divided by 360 days. PDC was defined similarly to MPR with the number of overlapping days supply subtracted from the numerator. Persistence was defined as time to discontinuation of biologics overall, or by individual biologic, with a 90-day permissible gap.

RESULTS: Overall, 2,130 patients were treated with a biologic: 282 (13%) had mild, 116 (5%) moderate, and 49 (2%) severe PsO; 1,683 (79%) were unable to be classified. Overall, patients had an MPR of 74%, a PDC of 70%, and a persistence of 298 days. Patients with severe or moderate disease vs. mild had lower adherence (MPR: 65% [severe], 72% [moderate], 77% [mild]; PDC: 59% [severe], 67% [moderate], 73% [mild]) and persistence (263 [severe], 292 [moderate], 311 [mild] days). Looking at each individual biologic, MPR (PDC) ranged from 67% (64%) for etanercept (N=677), 69% (66%) for adalimumab (N=982), 72% (67%) for ustekinumab (N=373), to 87% (81%) for infliximab (N=98); persistence ranged from 275 days for adalimumab, 280 for etanercept, 288 for ustekinumab, to 299 days for infliximab.

CONCLUSIONS: PsO patients treated with biologics had modest adherence and persistence to the biologics overall, with severe or moderate patients demonstrating lower adherence and persistence than mild patients. Adherence and persistence varied by individual biologic. There is an opportunity to improve adherence and persistence among moderate-to-severe PsO patients treated with biologics, which could result in improved patient outcomes.

SPONSORSHIP: Eli Lilly.

L4 A Criterion-Based Approach to Systematic and Transparent Comparative Effectiveness Research: A Case Study in Psoriatic Arthritis

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BACKGROUND: Psoriatic arthritis (PsA) is a condition for which many treatments are available. Indirect treatment comparisons (ITCs) are used to compare 2 or more treatments when no direct comparison is available. However, to provide appropriate comparisons, the transitivity assumption must be met.

OBJECTIVE: This research aimed to develop a criterion-based approach to evaluate potential deviations to transitivity and select appropriate studies for ITC. PsA was used as a case study to demonstrate study selection for ITC with this technique.

METHODS: We developed a method to determine the plausibility of trial comparison and applied it to 18 RCTs, comparing apremilast to 7 other therapies in PsA. Corresponding to the typical application of ITC, no head-to-head clinical studies were available for these comparators. Seven criteria were evaluated to include studies in the ITC: (1) inclusion/exclusion criteria, (2) clinical trial design and follow-up, (3) baseline characteristics, (4) genetic severity subgroups, (5) prior therapies, (6) concomitant and post-trial treatment, and (7) placebo response. The evaluation considered that several key assumptions must be respected to enable the generation of robust and reliable estimates using ITC. In addition to technical assumptions, the ITC must respect the similarity/transitivity assumption, where imbalanced baseline characteristics and other trial design differences may lead to confounding bias. Often technical assumptions are valid and statistical feasibility is evaluated without considering transitivity.

RESULTS: The selected studies all used placebo as a common comparator, and the outcome variables of interest were available across all studies, allowing construction of the ITC network. However, most studies were proven to have some level of deviation to transitivity. Most deviations were related to trial design (including crossover, time of efficacy assessment and follow-up) and population differences (baseline disease characteristics, prior and concomitant medications, and placebo response rates). Even if the technical feasibility was acceptable, most studies could be considered incomparable to apremilast studies.

CONCLUSIONS: The level of deviation to transitivity often results from multiple issues. Transitivity assumptions must be evaluated thoroughly, as the confounding bias is often under-evaluated when performing ITC.

SPONSORSHIP: Celgene.

L5 Healthcare Costs Among Biologic-Naive Patients Initiating Apremilast or Biologics for the Treatment of Psoriatic Arthritis

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BACKGROUND: Apremilast is an oral, non-biologic medication indicated for the treatment of psoriatic arthritis (PsA). Information on the real-world healthcare costs associated with apremilast use compared to biologic PsA treatments is limited.

OBJECTIVE: To compare real-world healthcare costs between patients initiating apremilast or biologics among commercially insured biologic naive PsA patients in the United States.

METHODS: This retrospective study selected adult PsA patients initiating apremilast or biologics (index date) within the January 2013-June 2016 Truven Health MarketScan claims databases. Patients were required to be apremilast/biologic naive in the 12-month pre-index period and have continuous enrollment in the 12-month pre- and post-index periods. Biologic patients were propensity score matched up to 2:1 to apremilast patients. Healthcare costs were measured by type of service (inpatient, outpatient, and outpatient pharmacy) and reported per-patient per-month (PPPM) while the patient was persistent on their index treatment and during the 12-month post-index period. T-tests were used to evaluate the statistical significance of differences for continuous variables.

RESULTS: In total, 381 apremilast patients were matched to 761 patients initiating biologics. Baseline characteristics were similar in both cohorts: mean age 51 years, 60% female, mean Charlson Comorbidity Index score 0.6. While persistent on therapy, apremilast patients had significantly lower mean all-cause PPPM total healthcare costs ($3,328 vs. $5,050; $P<0.001$), which were driven by significantly lower outpatient pharmacy costs ($2,446 vs. $3,732, respectively; $P<0.001$) and other outpatient services costs ($528 vs. $788; $P<0.05$), which included services such as radiology, infusion administrations, rehabilitation and physical therapy. Total healthcare costs and total outpatient pharmacy costs in the 12-months post-index period were also significantly lower for apremilast users compared to biologics users ($35,764 vs. $48,479; $24,068 vs. $35,723, respectively; $P<0.001$).

CONCLUSIONS: Apremilast users had significantly lower total healthcare costs, which were driven by lower pharmacy costs and other outpatient services costs, compared to patients initiating biologics for the treatment of PsA.

SPONSORSHIP: Celgene.

L6 Minimal Clinically Important Difference for Work Productivity and Activity Impairment Questionnaire in Psoriasis Patients

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BACKGROUND: Anti-psoriatic biologic therapies can positively impact work productivity, as measured by the work productivity and activity impairment questionnaire for PsO patients (Work Productivity and Activity Impairment [WPAI-PsO]), but the clinical meaningfulness of reported improvements are unknown due to the lack of publications reporting minimal clinically important differences (MCID).

OBJECTIVE: Determine MCIDs for WPAI-PsO components using results from three phase 3 trials of ixekizumab (IXE).

METHODS: MCIDs for WPAI-PsO components were derived using treatment agnostic data from patients previously described by Gordon and colleagues. The analysis included patients randomized to placebo (PBO) and both IXE treatment groups (IXE either every 2 weeks or 4 weeks) from an integrated database of three phase 3 trials (UNCOVER-1/-2/-3). WPAI-PsO was administered at baseline and week 12 for UNCOVER-1/-2/-3, and at weeks 24, 36, 52, and 60 in UNCOVER-1/-2. MCIDs for WPAI-PsO components through week 12 were derived using the anchor-based method and supplemented with the distribution-based method. Validity of anchors was evaluated using correlation (Pearson, Spearman, Bi-Serial), analysis of covariance (ANCOVA) modeling, and logistic modeling against WPAI domains (absenteeism, presenteeism, work productivity loss, and activity impairment). MCIDs were triangulated using receiver operating characteristics (ROC) and distribution-based methods.

RESULTS: 3,126 patients were included in the analyses (PBO: 792, IXE: 2,334). Psoriasis area and severity index (PASI) and static physician's global assessment (sPGA) were shown to be valid anchors. Significant differences in WPAI components were observed between patients meeting clinically meaningful improvement in sPGA and PASI (all $P<0.001$). ROC analyses suggested a 20% improvement in work productivity loss or activity impairment components best represented the benefit of meeting a clinical meaningful improvement in PASI and sPGA. The distribution-based method supports the results of the anchor-based method.

CONCLUSIONS: MCIDs for the work productivity loss and activity impairment components of WPAI-PsO were both estimated to be 20% in patients with PsO. These estimates will make WPAI-PsO results more meaningful and actionable for payers, both public and private.

SPONSORSHIP: Eli Lilly.

L7 Comparison of Real-World Healthcare Costs Among Biologic-Naive Psoriasis Patients Initiating Apremilast or Biologics

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BACKGROUND: Few studies have described the real-world healthcare costs associated with apremilast compared to biologic treatments among patients with psoriasis (PsO).

OBJECTIVE: To describe and compare healthcare costs between biologic naive adults initiating apremilast or biologics for the treatment of PsO.

METHODS: This retrospective study evaluated biologic naive PsO patients initiating apremilast or biologics (index date) in the January 2013-June 2016 Truven Health MarketScan Research Databases. Patients were required to be apremilast/biologic naive at index and have 12 months of pre- and post-index continuous enrollment. Apremilast users were propensity score matched up to 1:2 to biologic users. Total healthcare costs were measured by type of service: inpatient, outpatient (office visits, laboratory tests, other services) and outpatient pharmacy. Costs were described per-patient per-month (PPPM) while the patient was persistent and during the 12-month post-index period. T-tests were used to evaluate the statistical significance of differences for continuous variables.

RESULTS: In total, 703 biologic naive PsO patients initiating apremilast were matched to 1,378 biologic naive PsO patients initiating biologics. Patient characteristics were similar between cohorts (mean age 49 years, 50% female, mean Charlson Comorbidity Index score 0.4). While persistent on therapy, PPPM total healthcare costs were significantly lower among apremilast patients compared to biologic patients ($3,426 vs. $5,649; $P<0.001$). Compared to biologic users, apremilast

users had significantly lower PPPM outpatient pharmacy costs ($2,478 vs. $4,922; $P<0.001$) and significantly lower PPPM outpatient medical costs ($407 vs. $640; $P<0.05$). Differences in outpatient medical costs were due to significantly lower PPPM other outpatient services costs, which included services such as radiology, infusion administrations, rehabilitation and physical therapy ($272 vs. $488; $P<0.05$). During the 12-month post-index period, total outpatient pharmacy costs ($23,376 vs. $41,803; $P<0.001$) and total healthcare costs ($32,304 vs. $49,875; $P<0.001$) were significantly lower for apremilast patients compared to biologics patients.

CONCLUSIONS: Compared to biologic naive patients initiating biologics for the treatment of PsO, apremilast users had significantly lower total healthcare costs due to lower outpatient pharmacy costs and lower outpatient medical costs while persistent on therapy and during the 12-month post-index period.

SPONSORSHIP: Celgene.

L8 Persistence and Adherence with Subcutaneously Administered Biologics Among Biologic-Naive and Biologic-Experienced Patients with Psoriatic Arthritis: Analyses from a U.S. Claims Database

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BACKGROUND: Patients with psoriatic arthritis (PsA) often switch between multiple biologics due to a need for better disease control. There are limited real-world data on the persistence and adherence with biologics in biologic-naive and experienced patients with PsA.

OBJECTIVE: To assess the persistence and adherence with biologics among biologic-naive and experienced U.S. patients with PsA who initiated a subcutaneous (SC) biologic.

METHODS: Patients with ≥1 pharmacy claim for a SC biologic FDA-approved for PsA between 01/15/2016 and 01/31/2017 were identified in the Truven Health Analytics MarketScan Commercial and Medicare Supplemental Databases. Eligible patients were aged ≥ 18 years at the time of biologic initiation (index date) and continuously enrolled with medical and pharmacy claims ≥ 12 months prior to (baseline period) and ≥ 6 months after the index date. Patients had ≥ 1 PsA diagnosis (ICD-9-CM 696.0 or ICD-10-CM L40.5x) and no pharmacy claims for the index biologic during the baseline period. Patients were assigned to a cohort by baseline biologic use (naive vs. experienced). Biologic discontinuation, number of days persistent and adherence (proportion of days covered) with the index biologic were evaluated over 6 months.

RESULTS: Of 2,208 eligible biologic initiations, 1,231 (55.8%) were in naive patients and 977 (44.2%) in experienced patients. Patients initiated adalimumab (naive, 55.6%; experienced, 26.7%), certolizumab pegol (3.9%; 12.6%), etanercept (30.1%; 22.3%), golimumab (2.4%; 6.6%) and secukinumab (7.9%; 31.8%). In the naive group, the 6-month discontinuation rate was lowest with secukinumab (12%), followed by adalimumab (16%), golimumab (20%), etanercept (24%) and certolizumab pegol (25%). In the experienced group, the 6-month discontinuation rate was lowest with secukinumab (12%), followed by adalimumab (17%), golimumab (17%), certolizumab pegol (18%) and etanercept (20%). Mean days persistent on the index biologic ranged from 148 (certolizumab pegol) to 163 (secukinumab) days in naive patients and from 155 (etanercept) to 165 (secukinumab) days in experienced patients. In both groups, the mean proportion of days covered was similar among secukinumab, adalimumab, etanercept and golimumab (naive, 0.73-0.76; experienced, 0.73-0.77) and lowest for certolizumab pegol (0.55; 0.65).

CONCLUSIONS: Patients with PsA who initiated secukinumab had the lowest discontinuation rate and highest mean number of days persistent over 6 months compared with the other SC biologics assessed, regardless of prior biologic use.

SPONSORSHIP: Novartis Pharmaceuticals.

L12 The Patient Journey for Patients Diagnosed with Psoriasis Who Receive a Biologic Prescription: Results from a Retrospective U.S. Database

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BACKGROUND: Most psoriasis (PsO) patients are candidates for topical treatment. If topical treatment does not elicit an adequate response or if it is not practical, systemic therapy (including orals or biologics) may be used.

OBJECTIVE: Describe the patient treatment journey for patients diagnosed with PsO who receive a biologic prescription.

METHODS: We identified patients with a PsO diagnosis (ICD-9-CM 696.1 or ICD-10-CM diagnosis codes L40.0, L40.8, L40.9) in a database of 39 Integrated Delivery Networks across the U.S. The analysis cohort included adults (≥18 years) at index topical date in the period 1/1/2011 and 06/30/2015, with either ≥2 PsO diagnoses or 1 PsO diagnosis by a dermatologist, absent confounding conditions before PsO diagnosis, no topical or oral prescription 6 months and 12 months, respectively, before index topical date, and continuous enrollment ≥12 months before and ≥36 months after index topical date.

RESULTS: We identified 33,397,271 adult patients in the period 1/1/2011 and 06/30/2015, of whom 143,133 (0.4 %) had at least one PsO diagnosis. 6,836 patients met all study inclusion criteria. 1,713 (25.1%) patients in the study cohort stopped topical treatment in the 36-month follow-up period. 797 (11.7%) received a switch/add-on to a biologic in the follow-up period. 344 (43.2%) patients first received an oral agent and then a biologic; the other 453 (56.8%) received a biologic without an oral agent first. The most common first biologic prescribed was adalimumab (45.7%), followed by etanercept (34.8%) and ustekinumab (14.7%). Topical steroids—class 1-2 (290/453; 64.0%) and class 3-7 (171/453; 37.7%)—were the most common topicals prescribed before a switch to a biologic prescription. Most commonly prescribed oral agents before biologic prescription included: methotrexate (193/344; 56.1%) for median of 127 days (IQR: 44-247) and prednisone (134/344; 39.0%) for median of 28 days (IQR: 14-43). Median time from topical to biologic start date was significantly shorter for patients directly switching from a topical to a biologic compared to patients who first switched to an oral agent and subsequently to a biologic prescription, compared to: 201 days (IQR: 50-516) and 480 days (IQR: 221-794.5), respectively ($P<0.0001$).

CONCLUSIONS: About 1 in 10 people being seen for psoriasis were switched from topicals to biologics over a 3.5-year period. The time to initiating the biologic was longer in those who were first switched to an oral psoriasis treatment. Maintaining patients on effective topical treatment may help minimize the need for a switch to biologics.

SPONSORSHIP: LEO Pharma.

L13 Clostridial Collagenase Ointment and Medicinal Honey Utilization for Pressure Ulcers in U.S. Hospitals

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BACKGROUND: Pressure ulcers (PUs) represent a considerable societal burden, affecting 2.5 million patients annually in the United States and accounting for up to $11 billion in healthcare costs. An important aspect of the treatment for PUs is debridement, which removes dead tissue from the wound, helping to promote healing. Among debriding methods, enzymatic debridement with clostridial collagenase ointment (CCO) has clinical advantages over other debriding methods by selectively removing necrotic tissue.

OBJECTIVE: Describe the utilization of CCO and medicinal honey debridement methods in real-world inpatient and outpatient hospital settings among pressure ulcer (PU) patients and compare the frequency of healthcare re-encounters between CCO- and medicinal honey-treated patients.

METHODS: De-identified hospital discharge records for patients receiving debridement and having an ICD-9 code for PUs were extracted from the U.S. Premier Healthcare Database. Multivariate analysis was used to compare the frequency of inpatient and outpatient revisits up to six months after an index encounter for CCO- vs. medicinal honey-treated PUs.

RESULTS: The study identified 74,524 inpatients and 25,955 outpatients with PUs. Overall, 54% of inpatients and 43% of outpatients had stages III or IV ulcers during their index visit. Among inpatients, N = 44,725 (60% of discharges) were treated with CCO, and N = 3,542 (5%) with medicinal honeys. CCO and medicinal honeys accounted for 1,826 (7%) and N = 773 (3%), respectively, of outpatients with PUs. In adjusted models, those treated with medicinal honeys had greater odds for inpatient readmissions (OR = 1.16, 95% CI: 1.07-1.25) after inpatient index visits, and outpatient re-encounters both after inpatient (OR = 1.37, 95% CI: 1.26-1.48) and outpatient (OR = 1.28, 95% CI: 1.05-1.57) index visits in six months of follow-up.

CONCLUSIONS: Patients with CCO-treated PUs returned to the inpatient and outpatient hospital settings less often compared with medicinal honey-treated PUs. These real-world data indicating less healthcare utilization support results from retrospective clinical outcomes studies demonstrating faster healing time for CCO- vs. medicinal honey-treated wounds.

SPONSORSHIP: Smith and Nephew Biotherapeutics.

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue *(e.g., RA, OA, Osteoporosis, Gout, Dupuytren's Contracture)*

M1 Treating Both Skin and Joint Disease Activity in Patients with Psoriatic Arthritis and Psoriasis: Experience from the Corrona Registry

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BACKGROUND: Managing patients with psoriatic disease requires a greater understanding of how joints and skin respond differently to therapy, as the precise relationship between joint and skin disease activity in this patient population is not well characterized.

OBJECTIVE: To investigate the relationship between joint activity and skin severity, and determine the impact of PsA therapy on skin and joint severity in PsA patients with current or a history of PsO.

METHODS: Enrollment visit data from the Corrona PsA/SpA registry were obtained from 3/21/2013-9/30/2016 on patients with PsA diagnosed by a rheumatologist with a history of PsO. PsA patients were evaluated for joint activity as defined by Clinical Disease Activity Index (CDAI) and skin severity as defined by Body Surface Area (BSA). Change in joint activity and skin severity from enrollment to 12 month visit were classified by change (improvement or worsening) in category of CDAI or BSA and changes in drug therapy were evaluated. CDAI categories were as Low: ≤ 10, Moderate: 1,022. BSA was categorized as Low: ≤ 3%, Moderate: > 3 to 10%, and High: > 10%.

RESULTS: 647 patients had a 12-month follow-up visit. 274 (42.3%) had CDAI > 10 and 218 (33.7%) had BSA > 3%. Patients in high joint activity were likely to have high skin severity ($P = 0.014$). The majority of patients (85%) were on DMARD therapy at enrollment. At 12 months, the majority (n = 369, 57%) of patients had no changes in therapy, and 54 (8.3%) reduced therapy. Improvement in joint severity was seen in 135 (21%) patients (median decrease in CDAI ≥ 5.5) and improvement in skin severity was seen in 138 (21%) patients (median decrease in BSA ≥ 4.5). Worsening of joint activity was seen in 113 (18%; median increase in CDAI ≥ 6.5) and worsening in skin severity was seen in 52 (8%; median decrease in BSA ≥ 4). No change in both joint and skin severity was seen in 281 (43%) patients.

CONCLUSIONS: The positive association between joint and skin severity suggests treatment decisions for PsA patients with PsO need to take into account both skin and joint efficacy. After 12 months, the majority of patients had no change in therapy and no change in either joint or skin severity. Further study beyond 12 months is needed to fully assess the real-world impact of these treatment interventions.

SPONSORSHIP: Corrona.

M2 Budgetary Impact Analysis of Real-World Dosing Patterns in Matched Cohorts of Rheumatoid Arthritis Patients Treated with Infliximab or Golimumab Intravenous Anti-Tumor Necrosis Factor Medications

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BACKGROUND: Infliximab (IFX) is more frequently selected than golimumab for IV use (GLM-IV) in pts with RA but differences in dosing and administration recommendations for these products may have budgetary consequences.

OBJECTIVE: This study aimed to determine budgetary impact of IFX and GLM-IV based upon real-world treatment patterns and commercial reimbursement in a matched sample of RA pts.

METHODS: Truven Commercial Claims and Encounters and Medicare Supplemental data were used to evaluate maintenance infusion interval, frequency of first or subsequent hour billing code and cost of infusions for adult RA pts starting a new episode of IFX (J1745) or GLM-IV (J1604). Adult pts with ≥ 12 months continuous enrollment before and after 1st IFX or GLM-IV claim (index) between 1/1/2014 and 3/31/2016 and no evidence of index medication use 12 months before index were studied. IFX and GLM-IV pts were matched 1:1 on index medication treatment duration, gender, payer type, prior-biologic use and post-index methotrexate (MTX). Payer paid drug plus administration cost was used applied to population treatment patterns. Descriptive statistics summarized key variables (mean, SD, median, n, %). Chi-squared tests determined differences between categorical variables and t-test was used for continuous variables.

RESULTS: A total of 1,094 matched pts were identified (n = 547 GLM-IV; n = 547 IFX). In both groups, median age was 56 yrs; 82% were female and 38% had no prior biologic use. Mean (SD) follow-up was 609 (161) days (d) for GLM-IV and 613 (163) d for IFX. Mean (SD) duration of GLM-IV use was 396 (240) d and 397 (239) d for IFX. A total of 3,961 GLM-IV infusions and 4,716 IFX infusions were administered. Proportion of maintenance infusions given every 8 wk was 80% for GLM-IV vs. 39% for IFX; 6% of GLM-IV vs. 53% of IFX infusions occurred more frequently than every 8 wk ($P < 0.0001$). Mean drug plus administration cost per infusion was $5,846.10 (GLM-IV) and $5,443.66 (IFX). Mean GLM-IV administration cost was $224.26 with < 1% of infusions having a second hour billing code vs. IFX with mean administration cost of $360.36 and 96% of IFX infusions requiring a second hour billing code ($P < 0.0001$). Based upon the average maintenance infusion interval, GLM-IV pts cost approximately $10,507 less than IFX pts in the first year and approximately $6,774 less than IFX pts in subsequent years.

CONCLUSIONS: From the commercial health plan perspective, annual GLM-IV drug plus administration cost was less than IFX in RA pts due to differences in real-world dosing and administration. These findings have important implications for population health decision makers.

SPONSORSHIP: Janssen Scientific Affairs.

M3 Incidence Rate of Biologic/Targeted Synthetic Disease-Modifying Antirheumatic Drugs for Rheumatoid Arthritis, Preceding Therapy, and Time to Discontinuation in a Commercially Insured Population

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BACKGROUND: Guidelines for rheumatoid arthritis (RA) management focus on conventional synthetic (cs) disease-modifying antirheumatic drugs (DMARDs) and escalation to one or a sequence of biologic/targeted synthetic (b/ts) DMARDs, with a goal of achieving remission or low disease activity.

OBJECTIVE: To describe: (1) the incident rate of initiation of b/tsDMARD therapy; (2) use of csDMARDs in the year preceding initiation; and (3) time to discontinuation of b/tsDMARD therapy stratified by the number of different agents used in sequence.

METHODS: 15 million 2016 members were queried to identify members continuously enrolled 2013-2016 (4 years) and age 18 to 64 years on December 31, 2016. Members with ≥ 2 medical claims with a diagnosis code for RA were categorized as RA. All pharmacy and medical drug claims for these members were analyzed to determine the first incurred date (index date), if any, for a b/tsDMARD ≥ Jan 1, 2014. Claims for csDMARDs in the 365 days before index date were described. csDMARDs were defined as methotrexate (MTX), hydroxychloroquine, sulfasalazine, and leflunomide. Days covered by b/tsDMARDs were determined from days supply for pharmacy claims and lesser of observed claims interval or recommended dosing interval for medical claims. Discontinuation was defined as a 90 day therapy gap. Descriptive statistics were used to describe utilization data and Kaplan-Meier analysis for describing discontinuation among members initiating b/tsDMARD in 2014 and followed at least 2 years.

RESULTS: Of 3.25 million continuously enrolled members age 18 to 64 years, 26,098 (0.7%) were categorized as RA, of whom 10,143 (38.9%) had a claim for a b/tsDMARD, with 3,796 of 10,143 (37.4%) with index dates ≥ Jan 1, 2014, for an incidence rate of new initiation of 35.9 per year per 100,000 members age 18 to 64. In the year preceding initiation, 455 of 3,796 (12.0%) had no claim for a csDMARD, 1,384 (36.5%) MTX monotherapy, 443 (11.7%) other monotherapy csDMARD, 1,173 (30.9%) 2 csDMARDs and 331 (8.7%) 3 csDMARDs. Of 1,316 members initiating in 2014, including any switches, 27.9% had discontinued b/tsDMARDs by 6, 43.1% by 12, and 58.1% by 24 months. 334 of the 1,316 (25.4%) switched one or more times to a different b/tsDMARD and 35.9% of these members had discontinued by 24 months compared with 65.7% of the 982 of 1,316 (74.6%) who did not switch.

CONCLUSIONS: Because of the high b/tsDMARDs cost and response variability to individual agents, initiating, discontinuing, or switching therapy are critical decisions from the perspectives of drug costs and potential indirect RA costs. Health plans should evaluate whether their utilization management strategies encourage compliance with RA guideline recommendations.

SPONSORSHIP: Prime Therapeutics.

M4 Healthcare Resource Utilization and Costs of Rheumatoid Arthritis Treated with Infused Biologics: A Site of Care Analysis

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BACKGROUND: Infusible biologic therapies must be administered by a healthcare professional but may be delivered in different sites of care (SOC), providing patients and physicians with flexibility in treatment setting. Previous research has shown that biologic drug and administration costs can differ by SOC, but little is known about the characteristics or healthcare resource use of patients who receive biologics in these settings.

OBJECTIVE: To examine demographics, medication adherence, and specific healthcare costs of rheumatoid arthritis (RA) patients receiving biologics in different SOC.

METHODS: RA patients newly initiating an infusible biologic (abatacept, infliximab, rituximab, or tocilizumab) were identified in Truven Commercial Claims and Encounters database (1/1/2009-12/31/2013). Patients were required to persist on a single biologic for 12 months and their infusions had to be administered at the same SOC. Patients were grouped by SOC for analyses: physician office (PO), hospital outpatient department (HOPD), and home-based (HB). Patient demographics, adherence, annual healthcare resource utilization and costs were calculated for SOC groups.

RESULTS: A total of 3,656 patients were identified; the majority were female and commercially insured. Patients treated in the HOPD setting incurred significantly more outpatient visits per year (28.6 ± 15.8) compared to patients treated in the PO (26.3 ± 14.6) or HB (19.0 ± 15.0, $P < 0.05$) settings, and were also more likely to visit the ER than other groups (32.8% vs. 28.0% and 18.6% $P < 0.05$). No significant differences were observed in the number of prescription medications or inpatient visits across groups. The HOPD group incurred significantly greater total annual healthcare costs ($63,017) than the PO ($39,652) and HB groups ($46,816, $P < 0.05$). This trend in cost was observed for mean total outpatient costs (HOPD: $55,543; PO: $33,961 and HB: $39,605) and for mean total medical costs (HOPD: $59,139; PO: $36,410 and HB: $42,415). Adherence rates across agents and SOCs were high, with maintenance intervals and refill rates in line with labeled guidelines.

CONCLUSIONS: This study demonstrated that patients treated with biologics in the PO setting had lower mean total and categorical healthcare costs, while HB patients had lower outpatient and emergency room visit utilization. Further research into patient characteristics, comorbidities, clinical and quality outcomes will be helpful to identify the optimal infusion SOC for particular patient types.

SPONSORSHIP: Janssen Scientific Affairs.

M5 Rheumatoid Arthritis 2016 Prevalence, Drug Treatment, and Total Medical and Pharmacy Claims Expense in a 15 Million-Member Commercially Insured Population

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BACKGROUND: Health plans need to understand which categories of claims expense occur in excess for members with rheumatoid arthritis (RA) and, of these, which are potentially modifiable by improved drug therapy.

OBJECTIVE: To determine: (1) RA prevalence in a commercially insured population and (2) total claims expense by categories for RA members stratified by treatment and for all RA members compared with a matched sample of members without RA.

METHODS: From 15 million commercially insured members we identified individuals continuously enrolled 2013 to 2016 (4 years) and age 18 to 64 years. Those with ≥ 2 medical claims and those with no claims with a diagnosis code for RA were categorized as RA and notRA, respectively. A random sample of notRA was selected, matched 5:1 with RA by sex, age, and plan. RA members were categorized as utilizing a biologic or targeted synthetic (b/ts) disease-modifying antirheumatic drug (DMARD), conventional synthetic (cs) DMARD only, or no DMARD based on 2016 pharmacy and medical drug claims. All pharmacy claims were categorized by NDC codes, medical outpatient by HCPCS, inpatient by DRGs. Expense is the sum of insurer and member payments without adjustment for rebates or coupons.

RESULTS: Of 3.25 million continuously enrolled members, 26,098 (0.7% total, 1.1% of females, 0.4% of males) were categorized as RA, mean age 52.9, who had a 2016 PMPY total cost of $27,993. We selected 130,490 matched notRA members, mean age 52.9, who had $8,149 PMPY total cost. The RA members were categorized as: $8,761 (33.6%) utilizing b/tsDMARD, $51,911 PMPY; $9,135 (35.0%) csDMARD only, $15,068 PMPY; and $8,202 (31.4%) no DMARD, $16,841 PMPY. b/tsDMARDs accounted for $35,070 (68.2%) PMPY of the b/tsDMARDs utilizing group total costs and 59.2% of the difference in PMPY between all RA and notRA members. Of the excess PMPY cost for all RA members compared with nonRA members: other medical outpatient accounted for 19.9%, with leading categories imaging, office visits, musculoskeletal procedures and lab tests; medical inpatient accounted for 11.0%, leading categories musculoskeletal, infection, and cardiovascular stays; and other pharmacy accounted for 7.8%, leading categories NSAIDs and narcotic analgesics.

CONCLUSIONS: In this large commercial population about 0.7% of members have RA. Mean total cost of care claims expense for RA members is 3.5 times higher than members without RA, with b/tsDMARDs accounting for almost two-thirds of the difference. The results suggest opportunities for reduction in the direct costs of RA should be focused on strategies that optimize csDMARDs.

SPONSORSHIP: Prime Therapeutics.

M6 Economic Impact of Biologic DMARD Treatment for ACPA-Positive Patients: A Comparison of Abatacept and Adalimumab

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BACKGROUND: Anti-citrullinated protein antibodies (ACPA) are increasingly used as a routine tool at diagnosis of RA to estimate prognosis of disease progression. ACPA-positive (+) patients have more severe disease and are more likely to have higher RA-related medical costs. ACPA+ status can also affect DMARD efficacy.

OBJECTIVE: To estimate changes in RA-related medical cost after abatacept or adalimumab treatment in ACPA+ patients with RA.

METHODS: A three-step simulation model was applied. First, IMS PharMetrics Plus claims data linked to electronic medical record data (2010-2015) were used to estimate RA-related annual cost. Second, treatment efficacy of abatacept and adalimumab among ACPA+ patients with RA was measured based on clinical trial data. Efficacy was measured as the percentage of patients in remission, defined as CDAI ≤ 2.8. Finally, current literature was used to measure the change in annual cost from patients achieving CDAI remission.

RESULTS: In 859 newly diagnosed RA patients, annual RA-associated total cost was $,7940 for ACPA+ compared with $5,243 for ACPA-negative (–) patients (Δ = $2,697, $P = 0.002$). Based on a clinical trial in 646 patients, both abatacept and adalimumab were more efficacious in ACPA+ compared with ACPA– patients. However, abatacept improved outcomes mostly for those patients with the highest titre levels of anti-cyclic citrullinated peptide (anti-CCP, a surrogate for ACPA). Of those treated with abatacept, 51.2% of ACPA+ patients in the highest anti-CCP quartile (1,060-4,894 AU/mL) achieved CDAI remission at Day 728 compared with 30.8% for adalimumab. CDAI remission is associated with $956 RA-related cost per 30 days. Both abatacept ($783, 14.7% decrease in cost) and adalimumab ($658, 12.4% decrease in cost) reduced RA-related medical cost relative to a biologic-naive baseline with a $125 greater cost saving for abatacept. Examining patients with the highest titre levels, the cost savings were $1,048 (19.7%) for abatacept and $630 (11.9%) for adalimumab, a cost difference of $417 (2.4% of RA-related medical cost) per year.

CONCLUSIONS: Abatacept treatment in ACPA+ patients with RA improved functional status and decreased RA-related medical costs more than adalimumab.

SPONSORSHIP: Bristol-Myers Squibb.

M7 Analysis of Real-World Treatment Patterns in a Matched Sample of Rheumatology Patients with Continuous Infliximab Therapy or Switched to Biosimilar Infliximab

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BACKGROUND: Biosimilar infliximab (CT-P13) was first approved in Europe in 2013.

OBJECTIVE: This study compared treatment patterns of Turkish patients (pts) with a diagnosis of rheumatoid arthritis (RA) who initiated originator IFX (IFX) and either continued IFX or switched to CT-P13.

METHODS: Adult pts with ≥ 1 RA diagnosis code and IFX claim were identified in a national Turkish healthcare database. Eligible pts initiated and continued IFX (Continuer cohort; CC) or initiated IFX and switched to CT-P13 (Switch cohort; SC) during study period (Dec 1, 2010-Jun 1, 2016). The index date was defined as the CT-P13 switch date for SC or a random IFX date during the period of CT-P13 availability for CC. Cohorts were matched on age, sex, and number of IFX prescriptions during baseline. Discontinuation was defined as a switch to another biologic or no index biologic for ≥ 120 days without censoring. Patient demographics, discontinuation and switching were summarized with descriptive statistics.

RESULTS: A total of 697 pts initiating IFX were studied; 87% (N = 605) continued on IFX throughout the study period; 13% (N = 92) switched to CT-P13. Mean duration of IFX therapy during the baseline period was 422 days (CC) and 438 days (SC). Average duration of post-index follow-up was 16 months (CC) and 15 months (SC). During the combined baseline and post-index periods, median time on any IFX therapy was 1,080 days (CC) and 540 days (SC). Discontinuation post-index occurred in 19% (CC) and 87% (SC); mean time from index to IFX discontinuation/censoring was 276 days (CC) while the mean time from index to CT-P13 discontinuation/censoring was 132 days. Switching from IFX to CT-P13 occurred in 13% all IFX initiators (i.e., 100% of SC) on the index date; an additional 10% of the CC cohort switched to a non-IFX anti-TNF post-index. The majority of SC (82%) switched from CT-P13 post-index and 88% of those re-initiated IFX. Regional variation in switching was noted. Switching from IFX to CT-P13 occurred most frequently in Central Anatolia (26% of 697 IFX initiators). Switching from CT-P13 occurred in > 75% of SC patients in all regions except for Aegean (44% switched from CT-P13 to another biologic, predominantly IFX).

CONCLUSIONS: In Turkey, RA patients maintained on IFX had greater treatment persistence than those who initiated IFX and switched to CT-P13. High rates of CT-P13 discontinuation favored IFX re-initiation. Reasons for discontinuation are unknown, however regional differences in practice patterns were observed.

SPONSORSHIP: Janssen Scientific Affairs.

M8 Healthcare Resource Use and Costs Associated with Biologic Switching in Rheumatoid Arthritis

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BACKGROUND: Although biologics are effective in managing rheumatoid arthritis (RA), many patients experience at least one biologic switch during treatment. Biologic switching may occur due to clinical or non-clinical reasons. Changes to treatment regimens, such as switching, can have clinical and cost implications.

OBJECTIVE: This study examined the healthcare service utilization and costs incurred with switching from an anti-TNF medication in a population of RA patients.

METHODS: A retrospective analysis of RA patients identified in Truven Commercial Claims and Encounters database (1/1/2009 to 12/31/2013) was conducted. Patients were required to show evidence of new treatment initiation with a biologic medication (index date) and continuous eligibility 6 months pre-, and 12 months post-index. Patients were segmented into switchers and non-switchers, the latter being further divided into anti-TNF to anti-TNF (A-A) and anti-TNF to other mechanism of action (A-O) switch groups. Means, medians, and standard deviations of service utilization and cost outcomes were calculated over the 12-month post-index period; multivariate models controlling for demographics, biologic switch, and pre-period health, service use, and costs were constructed. Analyses were replicated in a biologic-naive sub-sample.

RESULTS: The overall switch group was more likely to utilize physician office, ER, and pharmacy services than the non-switch group in both the overall and biologic-naive samples ($P < 0.05$). Consequently, pts with a switch incurred greater total annual healthcare costs compared to the non-switch group in both the overall ($41,482 vs. $36,557; $P < 0.05$) and naive samples ($40,040 vs. $36,321; $P < 0.05$). Within the switch group, the A-O subgroup evidenced significantly greater outpatient, medical, pharmacy, and total healthcare expenditures compared to the A-A subgroup. Regression analyses revealed that increased baseline utilization and costs, worse health, and older age were associated with increased utilization and costs over the follow up period. Biologic switching was associated with an increase of approximately $4,000 in total healthcare costs per patient per year.

CONCLUSIONS: Biologic switching in RA is associated with increased healthcare costs. These findings indicate that switching agents, regardless of clinical or non-clinical reasons, may be accompanied by increased cost and utilization. Efforts to optimize patient response to initial biologic therapy and to reduce non-medical switching may help to mitigate costs.

SPONSORSHIP: Janssen Scientific Affairs.

M9 Network Meta-Analysis of the Efficacy and Safety of Sarilumab Monotherapy and Combination Therapy in Rheumatoid Arthritis Patients with Intolerance or Inadequate Response to Disease-Modifying Antirheumatic Drugs

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BACKGROUND: Sarilumab, a human mAb blocking the IL-6 receptor, was recently approved as monotherapy (mono) or in combination (combi) with conventional synthetic (cs) disease-modifying antirheumatic drugs (DMARDs) for treatment of adults with moderate-to-severe rheumatoid arthritis (RA).

OBJECTIVE: Network meta-analyses (NMA) were conducted comparing efficacy and safety of subcutaneous (SC) sarilumab 200 mg every 2 weeks (SAR200) mono vs. other DMARD (cs, biologic, janus kinase inhibitors) mono in patients with inadequate response (IR) or intolerance to csDMARD, and SC 150 mg q2w (SAR150) or SAR200 in combi with csDMARD vs. other DMARD combi in csDMARD-IR or tumor necrosis factor α inhibitor (TNF)-IR populations.

METHODS: Systematic literature review and NMA were conducted on 24-week efficacy and safety outcomes: American College of Rheumatology (ACR) 20/50/70 criteria; Health Assessment Questionnaire Disability Index (HAQ-DI) score; Disease Activity Score remission (DAS28 < 2.6); modified total sharp score (mTSS; also at 52 weeks); and overall rates of serious infections (SI) and serious adverse events (SAE). NMA with regression on baseline risk for csDMARD-IR and risk difference NMA in TNF-IR were conducted, using fixed- and random-effects models.

RESULTS: Fifty-five trials in csDMARD-IR (9 mono, 45 combi, 1 on both) and 10 trials in TNF-IR patients were identified. In csDMARD-IR, for all efficacy outcomes SAR200 mono was superior vs. adalimumab (ADA) mono, superior vs. csDMARD (but similar on HAQ-DI) and superior vs. sirukumab (SIR) SC 50 mg q4w mono on ACR20/50. SAR200 mono was similar to certolizumab (CTZ), etanercept (ETA), SIR SC 100 mg q2w, tocilizumab (TCZ) 8 mg/kg mono across efficacy outcomes. Both SAR150 and SAR200 combi were superior vs. csDMARD on all efficacy outcomes. SAR200 combi was superior to baricitinib (BAR) 2 mg, tofacitinib and CTZ combi on 24-week mTSS, but similar to BAR 4 mg, ADA, ETA, golimumab (GOL), infliximab and TCZ combi (all doses). In TNF-IR, SAR200 combi was superior to SIR 50 mg and BAR 2 mg on ACR50 and DAS28, and similar to abatacept, GOL, TCZ 4 mg and rituximab combi on ACR 20/50/70. Rates of SI/SAE appear similar for SAR150 and SAR200 vs. all active comparators in all populations.

CONCLUSIONS: Consistent with head-to-head MONARCH (NCT02332590) trial results, in this NMA, SAR200 mono had superior efficacy and similar SI/SAE rates vs. ADA mono, and at least similar efficacy and SI/SAE rates to other biologic DMARD. SAR150 combi and SAR200 combi had superior efficacy and similar SI/SAE rates vs. csDMARD and at least similar efficacy and SI/SAE rates to all other DMARD combi.

SPONSORSHIP: Sanofi and Regeneron.

M10 Healthcare Resource Use Among Rheumatoid Arthritis Patients Classified by Clinical and Biomarker Characteristics

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BACKGROUND: Current management of rheumatoid arthritis (RA) is often controlled by payer medical policy implemented through a pharmacy benefit manager in which symptomatic disease is sequenced: disease-modifying anti-rheumatic drugs (DMARDs) until failure, followed by anti-TNF-α until failure, and then alternative anti-TNF upon failure. Traditional medicine challenges the strategy of salvaging failure of drug of specific mechanism of action (MOA) with drug of same MOA. Recent clinical and molecular profiling suggest subsets of patients who may not benefit from this strategy; one example is patients characterized as early rapidly progressing RA (eRPRA).

OBJECTIVE: To assess the feasibility of identifying eRPRA patients and characterize their healthcare resource use (HRU) when treated with different biologic DMARDs (bDMARD): an anti-TNF or abatacept.

METHODS: A feasibility screener was sent to practicing rheumatologists to query for adult patients meeting the following criteria for eRPRA prior to first bDMARD: anti-CCP2 positivity, DAS28-CRP ≥3.2, symptomatic synovitis in ≥2 joints for ≥8 weeks, onset of symptoms ≤2 years; treated with abatacept or an anti-TNF. Patient characteristics and HRU in first 6 months following start of bDMARD were collected via case report form (CRF) and summarized for those treated with an anti-TNF or abatacept.

RESULTS: CRFs on 104 and 34 patients treated with an anti-TNF and abatacept, respectively, were collected. Mean age at RA diagnosis was 47.6 years and 48.7 years; time from RA diagnosis to eRPRA identification was 5.3 months and 4.8 months for anti-TNF and abatacept users. At bDMARD start, patients with eRPRA treated with an anti-TNF or abatacept, respectively, had mean swollen joint counts (SJC) of 7.3 and 8.0, tender JC of 10.0 and 12.1, ESR of 51.0 mm/hr and 52.3 mm/hr, CRP of 6.3 mg/L and 6.0 mg/L, and number of boney erosions of 1.0 and 2.1. The majority of anti-TNF (52%) and 35% of abatacept users had concomitant oral corticosteroids at start of bDMARD. A greater proportion of patients treated with anti-TNF had hospitalizations (87% vs. 82%), ED visits (88% vs. 85%), MRI (88% vs. 74%), ultrasound (88% vs. 74%), and x-ray (98% vs. 88%) during first 6 months of bDMARD treatment.

CONCLUSIONS: Although poorly defined in clinical practice, patients can be identified as eRPRA. Despite having greater disease severity at start of bDMARD, patients with eRPRA treated with abatacept tended to have lower HRU than those treated with an anti-TNF. However, this is a preliminary analysis and comparisons are warranted on a greater number of patients to identify statistically and clinically meaningful differences.

SPONSORSHIP: Bristol-Myers Squibb.

M11 Association of Activities of Daily Living and Treatment of Rheumatoid Arthritis with Disease-Modifying Antirheumatic Drugs from 2006 to 2013

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BACKGROUND: Rheumatoid arthritis (RA), an autoimmune inflammatory disease of the joints, affects 1.3 million adults in the U.S. and can result in debilitation and disability. The American College of Rheumatology Guideline for the Treatment of RA states that disease-modifying anti-rheumatic drugs (DMARDs) are strongly recommended for treatment of early and established RA. A commonly adopted quality measure of health plans include receipt of one ambulatory prescription for a DMARD in RA patients. They are more likely to report fair or poor general health, need help with personal care, and have health-related activity limitation than those without arthritis. ADL stages, in contrast to traditional ADL measurement, provides a hierarchically organized profile of activity limitations.

OBJECTIVE: To analyze the role of ADL limitations in the treatment of RA with DMARDs in the Medicare population

METHODS: This retrospective, cross-sectional study utilized Medicare Current Beneficiary Survey (MCBS) data from 2006-2013, linked to Medicare part A, B, and D data. The inclusion criteria consisted of diagnosis of RA, continuous enrollment, and community-dwelling in the calendar year of study. Exclusion criteria were enrollment in Medicare Advantage, age <18 years, and incomplete data. ADL and ADL Stages were calculated using self-reported difficulty with six activities. Covariates include sex, race, geographic region, level of education, and self-reported general health. Part D claims captured the outcome of DMARD use within the study year. Chi-square tests were conducted to compare baseline characteristics and multivariate logistic regression assessed association between ADL and DMARD use.

RESULTS: Of 1,664 RA patients, 1,059 met study criteria. In univariate analysis, age, geographic region, and self-reported general health showed statistically significant differences between the DMARD and non-DMARD users. The ADL stages were not found to be statistically significant in association with DMARD use in all the ADL stages. ADL Stage II had unadjusted OR 1.563 (95% CI: 0.983, 2.485) and adjusted OR 1.515 (95% CI: 0.916, 2.507). Analysis on absence or presence of at least one ADL showed non-significant association with DMARD use in unadjusted OR 1.274 (95% CI: 0.929, 1.748) and adjusted OR 1.243 (95% CI: 0.882, 1.752).

CONCLUSIONS: Drawing focus to self-reported activity limitations, uniquely captured in MCBS, can help elucidate disparities and associations in DMARD use among RA patients. Although analyses indicate no association between ADL stages and DMARD use, the finding of ADL Stage II may be of interest in further analyses.

SPONSORSHIP: None.

M12 Health Resource Utilization and Costs in BRCA-Positive Metastatic Breast Cancer Patients Treated in the Community Oncology Setting

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BACKGROUND: BRCA-mutated metastatic breast cancers (MBC) are treated with different modalities depending on hormone status. Patients can experience adverse events during treatment that lead to increased healthcare resource utilization (HRU).

OBJECTIVE: We assessed HRU and costs in patients with BRCA-mutated MBC who were either triple negative (TN) for estrogen receptor, progesterone receptor, and human epidermal growth factor receptor-2 (HER2) or hormone receptor-positive (HR+)/HER2-negative.

METHODS: This retrospective study examined U.S. community medical records from the Vector Oncology Data Warehouse of adult patients with BRCA-mutated MBC by line of treatment. HRU included annual hospitalization rates, emergency department (ED) visits, and infused supportive care drugs (e.g., anti-anemia/neutropenia). Costs (inflated for 2017$) were based on matched Health Care Utilization Project coded events. Logistic regression was used to assess predictors of each HRU, controlling for treatment group and demographic/clinical characteristics.

RESULTS: The study included 114 (57 TN and 57 HR+) patients. Median age at MBC diagnosis was 46 and 51 years for TN and HR+ respectively; overall about 79% were White. Clinical characteristics (including initial stage at diagnosis, performance status, or site of metastasis) were similar among groups. Data presented are for first-line treatment, indicating n (%). In HR+ patients, frequent treatments were aromatase inhibitors 14 (24.6), fulvestrant 10 (17.5), tamoxifen 7 (12.3), and capecitabine 5 (8.8). For TN patients, treatments were bevacizumab/platinum 10 (20.4), capecitabine 10 (20.4), carboplatin/gemcitabine 8 (16.3), carboplatin plus other 7 (14.3), and paclitaxel 5 (10.2). About 40% of patients in each group had at least 1 hospitalization, ED visits were reported by 8% of TN and 21% of HR+ patients, and HRU for infused supportive care were higher for TN patients (37% vs. 16%; $P<0.05$). For the TN vs. HR+ groups respectively, annual hospitalization cost was $29,458 vs. $44,897, ED visit costs were $2,412 vs. $5,559, and costs for infused supportive care drugs were higher for TN patients ($9,979 vs. $4,481; $P<0.05$).

CONCLUSIONS: Despite differences in treatment regimen, the utilization and cost of hospitalizations and ED visits were not significantly different for patients with TN or HR+ MBC. However, patients with TN MBC had significantly higher utilization and costs for infused supportive care drugs compared to those with HR+ disease, which demonstrates a need for more tolerable treatment options for these patients.

SPONSORSHIP: AstraZeneca.

M15 Comparison of Deflazacort and Prednisone/Prednisolone in Duchenne Muscular Dystrophy: Results from the Post Hoc Analysis of the Placebo Arm of Phase-3 ACT DMD

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BACKGROUND: Duchenne muscular dystrophy (DMD) is a rare, X-linked recessive genetic disorder which imposes a significant burden on patients due to lack of ambulation at an early age, lowered health-related quality of life (HRQOL) and a shorter life span.

OBJECTIVE: To compare the efficacy and safety of deflazacort versus prednisone/prednisolone using data from the placebo-arm of the Phase-3 Ataluren Confirmatory Trial in DMD (ACT DMD).

METHODS: A post hoc analysis of the placebo-arm of the phase-3 ACT DMD was undertaken to evaluate changes from baseline to week 48 in 6-minute walk distance (6MWD), timed function tests (TFTs; namely, 4-stair climb, 4-stair descend, supine-to-stand, 10 meter walk/run), North Star Ambulatory Assessment (NSAA), and parent-reported HRQOL measure of Pediatric Outcomes Data Collection Instrument (PODCI) domains. Total or individual domain scores were calculated for NSAA and PODCI. Mixed-model repeated measures analysis comparing deflazacort (n = 53) and prednisone/prednisolone (n = 62) was undertaken; a linear extrapolation of 48-wk changes in 6MWD was conducted until patients in the respective treatment groups reached a 6MWD of 0 meters or loss of ambulation (LOA), to project the impact of interventions on LOA.

RESULTS: Results from ACT DMD placebo arm data demonstrated mean differences from baseline to Wk-48 comparing deflazacort vs. prednisone/prednisolone in 6MWD (31.6 meters; $P=0.0484$), key TFTs (4-stair climb (-2.9 sec; $P=0.0189$), supine-to-stand (-2.6 sec; $P=0.0506$), 4-stair descend (-1.8 sec; $P=0.2040$), 10 meter walk/run (-0.1 sec; $P=0.9297$), NSAA total score (1.1; $P=0.1360$), Transfers/Basic Mobility domain of PODCI (1.7; $P=0.5515$) and Sports/Physical Functioning domain of PODCI (6.0; $P=0.0282$), favoring deflazacort. Most frequent treatment emergent adverse events observed include (deflazacort, prednisone/prednisolone): nasopharyngitis (11%, 27%), headache (19%, 18%), vomiting (19%, 18%), fall (15%, 19%), pain in abdomen, including upper abdomen (0%, 29%), pain in extremity (11%, 13%), cough (9%, 13%), pyrexia (8%, 13%), constipation (8%, 10%), diarrhea (9%, 8%). A mathematical model projecting the impact of prolongation of ambulation to age at LOA, showed an incremental delay in LOA of 3.8 yrs among patients on deflazacort (vs. prednisone/prednisolone).

CONCLUSIONS: A post hoc analysis of ACT DMD data suggests that deflazacort experienced significantly slower rates of functional decline over 48 weeks than those receiving prednisone/prednisolone

SPONSORSHIP: PTC Therapeutics.

M16 Dosing Patterns Associated with Deflazacort Observed in the Early Access Program for Patients with DMD in the United States

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BACKGROUND: Deflazacort (EMFLAZA) is the first Food and Drug Administration (FDA)-approved corticosteroid treatment for Duchenne muscular dystrophy (DMD) in patients ≥ 5 yrs of age in the U.S. Deflazacort is available both as tablet (6/18/30/36 mg) and oral suspension.

OBJECTIVE: To evaluate real-world dosing patterns associated with deflazacort in the Early Access Program (EAP) in the U.S.

METHODS: Deflazacort EAP was an open label study implemented between Sept 2015 and May 2017, per following inclusion criteria: patients ≥ 5 yrs of age with DMD who were ineligible/unable/otherwise unwilling to enroll in a clinical study while marketing application (for deflazacort) was under preparation/review; child or adolescent patients (< 18 yrs) weighed ≥ 13 kg, with body mass index (BMI) < 40 kg/m2, and were up-to date on childhood vaccinations; adult patients (> 18 yrs) had 18.5 kg/m2.

RESULTS: In total, 860 eligible DMD patient records were included in the analysis. Patient characteristics included mean age: 12.8 yrs, % prescribed tablet/oral suspension: 86.1%/13.9%, % prescribed once-daily dosing: 89.9%. Weight varied from 14.8-136 kg. Mean daily protocol-recommended dose vs. actual-prescribed dose was 40.4 mg (STD: 18.8 mg) vs. 27.0 mg (STD: 10.9 mg); the corresponding mean difference in daily protocol-recommended vs. actual-prescribed dosing was 13.3 mg (STD: 16.8 mg) across the cohort; this mean daily dose difference increased as the patient weight increased. Corresponding mean % variance of actual-prescribed dose from protocol-recommended dose was: 10-19 kg: +0.5%, 20-29 kg: -5.2%, 30-3 9 kg: -17.7%, 40-49 kg: -27.6%, 50-59 kg: -37.5%, 60-69 kg: -43.0%, 70-79 kg: -54.0%, 80-89 kg: -51.9%, 90-99 kg: -57.1%, 100-109 kg: -57.7%, 110-119 kg: -66.4%, ≥ 120 kg: -63.4%.

CONCLUSIONS: In this cohort of EAP patients on deflazacort, the actual prescribed dose was lower than the protocol-recommended dose and the variance increased with patient weight.

SPONSORSHIP: PTC Therapeutics.

M18 Cost-Effectiveness of Abaloparatide Versus Teriparatide for Prevention of Osteoporosis-Related Fracture: A U.S. Payer Perspective

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BACKGROUND: There have been limited options for active treatment and prevention of osteoporosis. Recently, the FDA approved the human parathyroid hormone-related protein (PTHrP) analog abaloparatide (TYMLOS) for daily injection.

OBJECTIVE: To determine the cost-effectiveness of abaloparatide (ABL) compared to teriparatide (TPTD) for the treatment of postmenopausal women with osteoporosis.

METHODS: A discrete event simulation model (DES) assessed the cost-effectiveness of ABL in women ≥ 50 years of age with osteoporosis using the U.S. private-payer perspective and 10-year time horizon. The model included three 18-month treatment strategies with placebo (PBO), TPTD, or ABL, each followed by 5-year treatment with alendronate (ALN). In the DES model, a patient could experience up to 1 vertebral, 1 wrist, 1 other major osteoporotic fracture (MOF), and multiple hip fractures following an initial fracture of the hip, vertebrae, wrist, or other MOF. For patients with hip fracture(s), there was a possibility they would die from hip fracture or enter a nursing home. Baseline patient population was based on the Abaloparatide Comparator Trial in Vertebral Endpoints (ACTIVE). Costs and utility values were derived from the literature. One-way and probabilistic sensitivity analyses were performed to test robustness and uncertainty of the model results.

RESULTS: Over the 10-year time horizon and 40,000 simulations for each treatment strategy, the DES model yielded average total discounted costs per patient of $13,443, $44,990, and $27,598 and quality-adjusted life years (QALYs) per patient of 6.742, 6.769, and 6.784 for PBO/ALN, TPTD/ALN, and ABL/ALN, respectively. Compared to TPTD/ALN, ABL/ALN was a dominant strategy, producing more QALYs while being less costly. Compared to PBO/ALN, ABL/ALN produced an incremental cost-effectiveness ratio which was 72% lower than that for TPTD/ALN ($337,200/QALY vs. $1,202,858/QALY). Probabilistic sensitivity analysis indicated that regardless of willingness-to-pay thresholds, ABL/ALN always remains a dominant treatment strategy compared to TPTD/ALN and also in subgroups across all age groups with or without prior fracture.

CONCLUSIONS: Abaloparatide is a cost-effective (dominant) alternative to teriparatide for the treatment of postmenopausal osteoporosis. Patients on ABL accrued lower incremental total costs and higher incremental number of QALYs than TPTD over a 10-year time horizon. Model results may be used to optimize care management decisions for treating patients with osteoporosis.

SPONSORSHIP: Radius Health.

M19 Osteoporosis-Related Fracture Events in the United States

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BACKGROUND: Osteoporosis is an important public health problem. Even patients who are hospitalized for fracture remain subsequently untreated. Current evidence on the occurrence of fractures is required to help payers and policymakers prioritize access to therapies and programs that can reduce the burden and cost of osteoporosis.

OBJECTIVE: To evaluate the magnitude of claims-based osteoporosis-related fractures in the U.S. population overall and across subgroups including race/ethnicity, age, sex, and fracture site.

METHODS: The current study used 2015 data from Medicare Standard Analytic Files (SAF), a national representation of all Medicare Fee for Service claims. In addition, commercial claim estimates were built using the following sources of data: Medicare SAF Inpatient Claims, Health Care Cost Utilization Project, CMS Hospital, U.S. Census Bureau demographics by ZIP code, and commercial claims from several states. Estimates of closed fractures were quantified for hip, clinical vertebral, wrist, and other skeletal sites associated with fragility fractures that commonly occur in patients with osteoporosis using the following principal diagnosis ICD-9 codes: 805.x, 805.2x, 805.4x, 805.8x, 813.2x, 813.4x, 813.8x, 808.8x, 810.0x, 811.0x, 812.0x, 812.2x, 812.4x, 814.0x, 815.0x, 821.0x, 822.0x, 823.0x, 823.2x,823.4x, 823.8x.

RESULTS: More than 2 million fractures occurred in 2015. Women accounted for 70% of fractures and 74% of the cost. Although there was a high occurrence of vertebral fractures in both men and women (18%), nonvertebral fractures represented (82%) of all fractures. They included wrist (16%), hip (20%), pelvic (7%), and other (33%; humerus, clavicle, and hand/fingers). Over 38% of the total diagnostic claims for fractures occurred in patients living in the southern region of the United States. On a state-by-state basis, Florida (8%), Texas (7%), and New York (6%) contributed to a majority of fracture events. Most fractures occurred in patients 75-84 years of age; however, the number of fracture-related claims, while steady over time compared with previous studies, remained highest in white women.

CONCLUSIONS: The number of osteoporosis-related fractures has escalated as predicted by earlier epidemiological studies. Treatment of osteoporosis and educational efforts in raising awareness about both osteoporosis and osteoporosis-related fractures should include all skeletal sites. Further, increased access to available therapies is warranted in the subpopulations with the highest risk.

SPONSORSHIP: Radius Health.

M20 Cost-Effectiveness of Abaloparatide for the Treatment of Postmenopausal Women with Osteoporosis

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BACKGROUND: Osteoporotic-related fractures are a significant burden on the healthcare system. The number of persons over age 65 will double within 2 decades, with likely increases in associated costs of illness. Recently, the FDA approved abaloparatide, a human parathyroid hormone-related protein (PTHrP) analog, for daily injection.

OBJECTIVE: To estimate cost-effectiveness of abaloparatide (TYMLOS) versus other treatments for postmenopausal osteoporotic women.

METHODS: A validated Markov microsimulation model was developed to estimate the cost-effectiveness of abaloparatide with a lifetime horizon. The primary analysis compared abaloparatide to teriparatide (TPTD) and to no treatment. Patients were assumed to receive abaloparatide and TPTD for 18 months, similar to the treatment period in ACTIVE. In the secondary analysis, comparison was made to denosumab (DMAB) and generic alendronate (ALN). The effect of DMAB

on fracture risk was derived from the FREEDOM trial; the effect of generic ALN was derived from the NICE appraisal. Patients began in the "no fracture" state and had, every 6 months, a probability of a fracture of the hip, vertebrae, wrist, or other site or of dying. High-risk patients—those with 10-year risk of a major osteoporotic fracture ≥20% based on IOF FRAX tool or those with prevalent vertebral fractures and BMD T-score ≤−2.5—were evaluated. Abaloparatide's price is not available in the EU, so several scenarios, including parity to TPTD and 10-30% discount/premium were considered. Costs and utility values were derived from the literature. One-way and probabilistic sensitivity analyses were performed to test the robustness and uncertainty of the model results.

RESULTS: Over the lifetime horizon and 1,000,000 total trials for each analysis, abaloparatide was cost-saving (lower costs for more QALYs) compared with TPTD. Abaloparatide remained cost-saving for a cost up to 119% of TPTD cost. The cost per QALY of abaloparatide compared with no treatment was under the WHO-recommended threshold. In women with prevalent vertebral fracture and BMD T-score ≤−2.5, abaloparatide was cost-effective at a threshold of €50,000 per QALY gained compared to DMAB and generic ALN and across all age groups.

CONCLUSIONS: In patients at high risk of fragility fractures, abaloparatide is a cost-effective (dominant) alternative to TPTD as well as to DMAB and generic ALN. Treatment decisions in consideration of risk status may decrease the cost of illness associated with osteoporotic fractures.

SPONSORSHIP: Radius Health.

M21 Challenges in Osteoporosis Awareness and Management: Results from a Survey of U.S. Postmenopausal Women

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BACKGROUND: Osteoporosis-related fractures are a serious public health burden leading to excess morbidity, excess mortality, and high costs for postfracture care. Evaluation of risks and timely management of disease are of paramount importance for the improvement of long-term health outcomes.

OBJECTIVE: To evaluate perception of osteoporotic fracture risk in a population of U.S. postmenopausal women and to gain insight on challenges associated with diagnosis and treatment.

METHODS: An online survey of U.S. postmenopausal women ≥50 years of age (n=1,012) was conducted by Harris Poll in collaboration with the National Osteoporosis Foundation (NOF) and Healthywomen between March 31 and April 17, 2017. A weighted sample of U.S. census including those with and without osteoporosis was used. The survey was designed to evaluate postmenopausal women's understanding of osteoporosis and its link to fractures.

RESULTS: Approximately 50% of the survey participants (501 of 1,012) were postmenopausal women with a self-report of physician diagnosis of osteoporosis (PMO), and half of those (250 of 501) were ≥65 years of age. Among all surveyed women, the most common comorbidities as self-reported were hypertension, thyroid disease, respiratory disease, and diabetes. Fifty-six percent (280 of 501) of PMO and 20% (99 of 511) of women who did not report having a PMO diagnosis experienced a fragility fracture. Of women who experienced a fragility fracture, the majority received initial care in the emergency room or by primary care physicians. The majority (96%) of women with a first fracture did not recall being told by their physician that their fracture may be related to osteoporosis. Subsequent to the diagnosis of a fragility fracture, about a third of women were not being referred for a follow-up visit; this varied by the specialty of the treating physician (orthopedic surgeons: 44%; primary care physicians/geriatricians (22%); emergency room physicians (18%). The majority (55%) of survey participants disagreed that a fracture is a potential sign of more fractures to come; some believed that only hip and back fractures are associated with osteoporosis.

CONCLUSIONS: These survey results reveal lack of awareness of osteoporotic fracture risk among postmenopausal women. There is poor understanding that a fragility fracture may be indicative of osteoporosis and that it increases future fracture risk. There is a need for more education among postmenopausal women to recognize that a fracture is a sentinel event that requires further evaluation and interventions to reduce the risk of subsequent fractures.

SPONSORSHIP: Radius Health.

N00-N99 Diseases of the Genitourinary System *(e.g., ESRD)*

N2 A Markov Model Using Retrospective Claims Database Analysis to Assess the Budget Impact of the Treatment of Mirabegron in a U.S. Health Plan

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BACKGROUND: Overactive bladder (OAB) is a common condition, affecting an estimated 16.5% of adults in the United States. Mirabegron, a beta-3 adrenergic agonist, was approved by the FDA in 2012 for the treatment of OAB based on phase 3 trial evidence of significant improvement in incontinence episodes, micturition frequency, and volume voided per micturition. Maximal response with mirabegron is achieved at 12 weeks, although guidelines recommend reviewing oral OAB treatment after 4 to 8 weeks to ensure it is tolerable and efficacious. As such, premature oral treatment changes may be made before allowing patients to achieve maximal response, as demonstrated in clinical trials.

OBJECTIVE: This analysis utilizes a retrospective analysis of claims data to inform a Markov model to assess the impact of an inadequate mirabegron evaluation period.

METHODS: A retrospective analysis of OptumHealth administrative claims data from January 2013 to March 2016 was conducted to inform a Markov model to simulate OAB treatment costs. Patients were included if they were 18 years or older with at least two medical claims with an OAB diagnosis and received at least one pharmacologic or surgical treatment for OAB. Transition probabilities were estimated for patients who had a ≥12-week evaluation period and a <12-week evaluation period. Total OAB-related medical and medication costs were simulated for a plan with ≥12-week evaluation period relative to a plan with <12-week evaluation period. Medication costs for oral treatments were based on the most recently published wholesale acquisition costs. OAB-related medical costs including those associated with OAB comorbidities and treatment-related adverse events were based on published literature.

RESULTS: Over three years in a hypothetical 1 million-member plan, compared to the scenario with suboptimal follow up, the scenario with ≥12 week follow up resulted in a reduction in per member per month (PMPM) costs of $0.05. Specifically, over three years, OAB-related medical costs decreased by $2.69M and medication costs increased by $0.96M. Overall, total costs decreased by $1.73M. The model also showed decreases in costs for onabotulinumtoxinA ($0.98M), percutaneous tibial nerve stimulation ($0.34M), and sacral neuromodulation ($1.51M).

CONCLUSIONS: This model suggests that a longer (≥12 week) evaluation period for patients taking mirabegron projects lower overall medical costs for OAB.

SPONSORSHIP: Astellas Pharma Global Development.

R00-R99 Symptoms, Signs, and Abnormal Clinical and Laboratory Findings Not Elsewhere Classified *(e.g., Pain, Opioids, Vasomotor, Urticaria, Nausea & Vomiting)*

R1 Burden of Postoperative Nausea and Vomiting Associated with Acute Postoperative Pain Treatment

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BACKGROUND: Post-operative nausea and vomiting (PONV) is a source of significant burden and patient discomfort in inpatient settings, with use of opioids for post-operative pain management considered an established risk factor for PONV. Despite the widely known prevalence of PONV in inpatient settings, there is a lack of current, comprehensive data on the clinical and economic burden of PONV.

OBJECTIVE: Determine the incremental cost and resource use burden during inpatient stays among surgical procedures with high parenteral opioid use.

METHODS: We conducted a retrospective inception cohort study using the Premier Perspective Hospital Database of inpatient stays between July 2015 and June 2016, among patients >18 years old, with at least one surgical procedure of interest falling into 1 of 5 groups: general/colorectal, orthopedic, OB/GYN, cardiothoracic/vascular, and urologic, and ≥1 dose of parenteral fentanyl, morphine, or hydromorphone for acute postoperative pain (APP). Patient, treatment, and stay characteristics were compared between those with and without PONV during the stay (nausea and vomiting associated ICD-9-CM or ICD-10-CM or receipt of antiemetic after day 1 of inpatient stay). Logistic regression was used to identify predictors of PONV, Poisson regression for length of stay (LOS), and generalized linear regression to estimate differences in adjusted inpatient costs of those with vs. without PONV.

RESULTS: A total of 592,127 stays met inclusion criteria ranging from 12,682 (urologic) to 178,380 (orthopedic). The rate of PONV was lowest for OB/GYN (44%) and highest for general/colorectal stays (72%). PONV occurred primarily among females, increased with ages younger than 55-64 and declined with age groups ≥65, and where patients had greater severity of illness (all $P<0.05$). Stays with PONV had longer LOS (ranging from 40% more days in the orthopedic to 71% more days in the general/colorectal and urologic groups) and readmission rates approximately 1.5x greater than those without PONV across all groups ($P<0.05$). Adjusted total inpatient costs ranged from $1,698 (OB/GYN) to $8,826 (cardiothoracic) higher and from 1.2 (orthopedic) to 1.4 (cardiothoracic) times higher than those without PONV.

CONCLUSIONS: High rates of PONV were observed across the 5 procedure groups. Overall, PONV resulted in significantly longer LOS, greater rates of readmission, and higher costs compared to encounters without PONV. APP treatments with better gastrointestinal tolerability profile can reduce the clinical and economic burden of PONV.

SPONSORSHIP: Trevena.

R2 Budget Impact Analysis of MorphaBond ER (Morphine-ARER) for the Treatment of Chronic Pain from a Managed Care Perspective

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BACKGROUND: The development of abuse-deterrent formulations (ADF) of prescription opioids (RxO) is an important step toward deterring inappropriate use of these medications. Morphine-ARER is an extended-release (ER) morphine sulfate tablet formulated to deter misuse/abuse via the intravenous (IV) and intranasal (IN) routes of administration.

OBJECTIVE: To estimate the potential financial impact to a hypothetical health plan of 10 million members 2 years after adding morphine-ARER to the health plan drug formulary.

METHODS: The model estimates incremental healthcare resource use (HCRU) associated with RxO misuse/abuse based on a health plan's RxO formulary coverage and utilization. RxO misuse/abuse rates, incremental HCRU and costs were informed by the 2015 National Survey on Drug Use and Health, an analysis of claims from Optum Health Care Solutions, Inc. (2013-15) and published literature. Proportions of RxO abuse cases attributable to morphine ER via IV and IN administration were obtained from 2015 RADARS and ASI-MV data. In the base case analysis, RxO formulary shares prior to adding morphine-ARER were based on 2016-17 Symphony Retail Prescription data. Morphine-ARER was assumed to comprise a total of 0.11% share in year 1 (taking 20% from branded and 0.2% from generic non-ADF morphine ER) and 0.20% share (30% from branded and 0.4% from generic non-ADF morphine ER) in year 2 after formulary adoption. Proportion of misuse/abuse cases deterred by morphine-ARER was assumed to be 90% via IV and 60% via IN administration. Sensitivity analyses were performed by varying morphine-ARER shares, and the proportion of RxO misuse/abuse cases deterred by morphine-ARER's physical/chemical barrier properties.

RESULTS: In the base case analysis, adding morphine-ARER decreased abuse-related health care costs for a health plan of 10 million members by $224,039 (–$0.00093 per-member-per month [PMPM]), offsetting the pharmacy cost increase of $63,782 (+$0.00027 PMPM), resulting in a net cost-savings of $0.00067 PMPM over 2 years. When generic morphine ER shares replaced by morphine-ARER were doubled, overall PMPM budget increase remained low (+$0.00049 PMPM). Adding morphine-ARER remained cost-saving even when the proportion of misuse/abuse cases deterred by morphine-ARER was reduced to 45% and 15% for IV and IN administration, respectively.

CONCLUSIONS: Placing morphine-ARER on a health plan's drug formulary may result in overall cost savings to health plans and those who pay their premiums. These results provide a framework to inform formulary decision on ADF RxOs.

SPONSORSHIP: Daiichi Sankyo.

U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts *(e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Med. Rec., Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)*

U1 Managed Care Professionals of the Future: What Are Future Doctors, Nurses, and Pharmacists Being Taught About Pain Management?

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BACKGROUND: Chronic pain is one of the largest health burdens, both personal and financial, in the U.S. Approximately 50 million people suffer from persistent pain and the annual economic cost is over $500 billion. Despite huge strides in understanding the

physiological aspects of pain, there is a major gap between that understanding and pain assessment and management. Those who teach on pain topics in schools of nursing, medicine and pharmacy agree that pain is a uniquely individual and subjective experience that depends on a variety of biological, psychological, and social factors. However, there is a lack of agreement on the quantity or scope of pain education topics to be covered.

OBJECTIVE: The objectives of this study were to (1) explore current practices in pain education within U.S. nursing, medical and pharmacy schools, (2) assess educational gaps, and (3) provide recommendations for pain education.

METHODS: This descriptive cross-sectional study focused on prelicensure programs in nursing, medicine and pharmacy. A survey, adapted from a list of learning objectives used by Mezei and colleagues (2011) to assess pain curricula at medical schools, was developed to determine the scope, quantity, and delivery of pain education. Part one of the survey focused on general pain education topics, while part two focused specifically on opioid education. This two-part survey was administered using a web-based platform to evaluate the depth and breadth of pain education. Descriptive statistics and analysis of variance (ANOVA) were used for analysis.

RESULTS: There were 120 surveys completed by institutions. Demographics varied by school type (private 55% and public 45%) and environment (urban 34% and rural 66%). Results showed the most common teaching methods were didactic lectures, as well as case-based activities and clinical experience. Pharmacy programs spent less time overall compared to nursing and medical programs in several teaching areas ($P<0.05$). Nursing programs reported more use of simulation-based learning and devoted more time to patient interviewing ($P<0.05$).

CONCLUSIONS: This study provides a benchmark for the current state of the coverage of pain management topics among U.S. pharmacy, medical and nursing schools. This is important in managed care settings because of the trend toward replacing inexpensive generic drugs with new and expensive drugs for pain treatment. Due to recent regulatory initiatives and legal precedents there must be a cautious balance between complex patient needs and the financial constraints of the managed care setting.

SPONSORSHIP: UNT Institute for Patient Safety.

U2 Healthcare Service Utilization and Costs of Certolizumab Pegol Versus Infliximab Treatment in Patients with Rheumatoid Arthritis and Crohn's Disease

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BACKGROUND: Prior U.S. retrospective claims analyses of rheumatoid arthritis (RA) and Crohn's disease (CD) treatment costs have shown infliximab (IFX) to be costlier than certolizumab pegol (CZP) across all sites of care (physician office, home, outpatient [OP]), primarily due to lower CZP drug costs.

OBJECTIVE: To assess one-year (yr) healthcare resource utilization (HRU) and costs incurred by RA and CD patients (pts) treated with CZP vs. IFX.

METHODS: Medical and pharmacy claims data (2008-2015) were derived from the Truven MarketScan database of insured pts meeting inclusion criteria: RA or CD diagnosis, treatment initiation (index date) with CZP or IFX (July 1, 2008-December 31, 2014), continuous eligibility ± 12 months around index date, and age ≥ 18 yrs. Mean one-yr visits (OP, inpatient [IP], emergency room [ER], and office) and costs (pharmacy, medical, and total healthcare) for the RA and CD cohorts were assessed using multivariate (MV) regression models adjusted for treatment (CZP/IFX), prior biologic use (yes/no), gender, age, baseline health, and baseline HRU.

RESULTS: 2,182 pts were treated with CZP (RA: 1,398; CD: 784) and 6,864 were treated with IFX (RA: 3,592; CD: 3,272). In both the RA and CD groups, prior biologic use was associated with more OP visits ($P<0.001$), ER utilization ($P<0.001$), and elevated total medical costs ($P<0.001$). Despite the CZP cohort having more biologic-experienced pts (RA: 74.0% [CZP] vs. 40.8% [IFX]; CD: 55.5% [CZP] vs. 17.3% [IFX]), CZP treatment was associated with fewer physician office ($P<0.001$) and OP ($P<0.001$) services compared to IFX, but a greater pharmacy spend ($P<0.001$) for both RA and CD patients. However, CZP treatment was associated with reduced mean total healthcare costs ($P<0.001$), with mean IFX RA costs $4,041 greater per pt per yr compared to CZP RA pts ($46,908 vs. $42,867, $P<0.001$), and mean IFX CD costs $2,080 greater per pt per yr compared to CZP CD pts ($59,085 vs. $57,005, $P<0.001$).

CONCLUSIONS: Although CZP-treated RA and CD patients had an elevated rate of prior biologic use, which has been correlated with more severe disease, annual total healthcare costs were higher for IFX-treated RA and CD pts. When compared with IFX treatment, CZP was associated with a $4,041 saving per RA pt per yr and a $2,080 saving per CD pt per yr.

SPONSORSHIP: UCB Pharma.

U3 Health Outcomes Impact of the Appointment-Based Model

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BACKGROUND: An emerging solution to resolve nonadherence issues is the Appointment-Based Model (ABM). The ABM is a pharmacy operations model that utilizes medication synchronization and an appointment with the pharmacist for a medication review. ABMs reduce the number of trips to a pharmacy, improve medication adherence and patient satisfaction. However, it is unknown whether enrollment in an ABM may impact healthcare utilization.

OBJECTIVE: This study investigated (1) whether participating in an ABM program was associated with an increase in adherence and (2) whether participating in an ABM program was associated with a decrease in healthcare utilization.

METHODS: The study period was July 1, 2013 to December 31, 2015. Two large pharmacy chains from the southern region of the U.S. served as the intervention (ABM) and control. Adult patients were included if they had their initial ABM (index) in the first 6 months of 2014. Patients had to be continuously enrolled 6 months pre- and post-index. The sample was limited to patients with a prescription for 1 of 3 medication classes; oral diabetes medications, statins, or medications from the renin-angiotensin system antagonist (RASA) class. Using a matched cohort design, logistic regression was used to determine whether ABM increased adherence (PDC ≥ 80%). Generalized linear models were used to compare enrollment in an ABM with healthcare expenditures (costs) and visits (counts).

RESULTS: 4,681 unique ABM patients were matched to controls; 1,023 in the oral diabetes group, 2204 in the statin group; and 2387 in the RASA group; groups were not mutually exclusive. Patients enrolled in an ABM had significantly increased odds of achieving PDC ≥ 80%: OR 2.66, 95% CI: 1.92-3.69 for diabetes class, OR 2.32, 95% CI: 1.91-2.81

for statin class and OR 2.26, 95% CI: 1.85-2.75 for RASA class. In the adjusted models, out-of-pocket costs were not significantly different between ABM and control. Additionally, participation in an ABM did not increase healthcare utilization visits. For expenditures, those in an ABM had reduced medical costs ($P<0.01$), and patients receiving medications for diabetes or RASA were significantly more likely to have reduced prescription costs ($P=0.01$, $P\leq0.01$, respectively).

CONCLUSIONS: Participation in an ABM significantly increased adherence for all patients, for all drug classes. Simultaneously, there was no significant difference in the increase in out-of-pocket costs, while there was a significant decrease in medical costs and most prescription costs.

SPONSORSHIP: Pfizer provided external research support.

U4 Analysis and Categorization of Escalations to a Clinical Pharmacist Based on Monthly Clinical Assessments in a Health System-Based Specialty Pharmacy

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PROBLEM DESCRIPTION: Studies have shown that comprehensive specialty pharmacy patient management programs including telephonic clinical assessments and counseling were associated with improved medication adherence and reduced overall healthcare costs. In most specialty pharmacies, monthly clinical assessments consist of a phone call made to patients when they are due for a refill. The patient answers a set of questions to ensure proper and safe medication use prior to arranging medication delivery. If problems are identified, the call is escalated to a clinical pharmacist for further assessment. An escalation matrix is necessary for timely and appropriate escalations to a clinical pharmacist when a problem is identified during the call.

GOAL: To optimize specialty pharmacy monthly clinical assessment workflow and documentation with the development of branching logic that evaluates effective, appropriate, and safe use of medications.

PROGRAM DESCRIPTION: The University of Illinois Hospital and Health Sciences System has an accredited Specialty Pharmacy Service (SPS) for patients with complex chronic disease. Services range from insurance benefit verification to monthly clinical assessments. During the monthly clinical assessment, a student pharmacist asks a standard set of questions on medication tolerability, number of missed doses, how the patient administers their medication, new medications, and their overall satisfaction with therapy. The student pharmacist records any problems in free text and escalates them to a clinical pharmacist. A retrospective analysis of free text responses was performed on clinical assessments from April through November 2015. Types and frequencies of pharmacist escalations were coded and categorized into groups.

OBSERVATIONS: 2,908 monthly clinical assessments were conducted and 361 (12.4%) were escalated to the pharmacist for clinical counseling. The most commonly reported reasons for escalation were problems with medication nonadherence (40.4% of escalations), medication tolerability (38.8%), medication administration (11.9%), drug interactions (7.5%) and hospitalizations (3.3%). 30 escalations were prompted from more than one issue.

FINDINGS/RECOMMENDATIONS: A revised monthly clinical assessment survey with extensive branching logic was developed by SPS to efficiently address and manage escalations across all specialty diseases. This change aims to improve documentation of escalations, refine pharmacist workflow, and facilitate data collection for accreditation and future studies.

SPONSORSHIP: None.

U5 Reviewing Estimates of Potential Cost Savings from Biosimilars

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BACKGROUND: Prescription drugs are a key driver of health care spending growth, driven in part by increasing spending on biologics. Biosimilars have the potential to reduce biologic prices through competition. While the biosimilar pipeline is expanding and Zarxio (filgrastim-sndz) was the first biosimilar to enter the U.S. market in September 2015, it is too early to assess the impact of biosimilars on spending empirically.

OBJECTIVE: To identify, review, and summarize model-based quantitative estimates and qualitative drivers of the potential cost savings from biosimilars in the peer-reviewed and grey literatures.

METHODS: Our search focused on model-driven, U.S.-based sources published 2006 to 2017. We conducted multiple searches in academic databases including PubMed for a range of terms used to refer to biologics approved via an abbreviated regulatory pathway (e.g., "biosimilar" and "follow-on biologic"), combined with terms focusing on the economic impact of biosimilars (e.g., "cost," "price," "savings," and "economic impact"). In addition, we reviewed reference lists and carried out forward searches. We abstracted key model assumptions such as price reduction and biosimilar uptake rates, estimated cost savings, and key drivers of savings.

RESULTS: We reviewed 150 resources and identified 15 with model-based estimates of biosimilar cost savings. We found that assumptions on biosimilar price relative to originator price ranged from 10-51% (mean 27%). Biosimilar market share assumptions ranged from 5-60% (mean 28%). Cost saving estimates as a share of total biologic spending ranged from 0.2-10.5% (mean 3.1%; or $3.3B of total 2016 biologic spending). Reviewed studies varied in their scope in terms of all biologics versus select classes and in terms of the entire U.S. health care system versus single large payers such as Medicare. The key drivers of biosimilar cost savings that were discussed but rarely included in cost savings estimates were number and timing of biosimilar entrants, patient and prescriber acceptability, higher biosimilar development cost, life cycle management strategies by the innovator manufacturers, changes in market size, shares, and prices over time, payer coverage and payment policies, cost sharing, and regulatory policies including interchangeability.

CONCLUSIONS: While biosimilars have the potential to reduce health care spending, there is significant variation in the magnitude of savings. This variation is driven by heterogeneity in key assumptions. New empirical research will be feasible with additional U.S. biosimilar entry.

SPONSORSHIP: Sandoz.

U6 Retrospective Analysis of Real-World Neurotoxin Utilization and Expenditures and Payer Perspectives on Management Opportunities in the United States

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BACKGROUND: In addition to cosmetic applications, botulinum toxin type A products are used to treat spastic movement disorders and various other neurological conditions. Several toxin products are currently marketed, but little real world information exists regarding utilization or health plan management of toxins.

OBJECTIVE: Examine real world data regarding utilization and cost of toxins in commercially-insured patients treated with botulinum toxins, and payer panel (PP) insights from a medical and pharmacy director group discussion in approved indications.

METHODS: This retrospective study examined medical and pharmacy administrative claims data from 3 regional health plans (4.5M lives) to evaluate utilization and cost of toxins. Qualifying patients were ≥2 years at index date, met eligibility criteria, with ≥1 paid claim for toxins during measurement period (1/1/2014-12/31/2016). The index date was the first toxin claim for each patient occurring during the measurement period. Patients were eligible for 6 months prior to and 1 year following index date and categorized based on indication, including all adult and pediatric uses. Results were reviewed with an independent PP, comprised of health plan medical and pharmacy directors.

RESULTS: 5,194 patients were included in the study (mean age 46 years; 74% female). Toxin costs totaled $14.7M. The most commonly used product was onabotulinumtoxinA (>90% of patients). Toxins were prescribed for conditions related to adult spasticity (47%), adult migraine (39%), adult cervical dystonia (7%), and any pediatric use (6%). Members averaged just over 2 claims annually, with highest annual utilization in adult migraine (3.2 claims), followed by adult cervical dystonia (2.8), adult spasticity (2.4), and pediatrics (1.9). Cost analysis considered differences in per unit billing costs, taking into consideration the variations in units associated with HCPCS codes for each product. Given these results, the PP provided insight regarding current and proposed management strategies for toxins.

CONCLUSIONS: Current toxin utilization favors a single product. The availability of other products offers flexibility to evaluate potential incremental cost savings and manage the toxin class in an evidence-based and financially advantageous manner, while allowing access for patients with conditions indicated for use of these products. In collaborative discussion, Medical and Pharmacy Directors determined these data support the potential benefit of implementing a clinical management strategy to manage toxins and optimize utilization of cost-effective therapies.

SPONSORSHIP: Ipsen Biopharmaceuticals.

U7 Cell and Gene Therapy Evaluation and Coverage Challenges

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BACKGROUND: Cell and gene therapy (C>) are fields of medicine that involve replacing, manipulating, or engineering cells and/or genetic material to fight disease. They offer customized disease treatment with the potential for curative results, but will create new process complexities that require extensive coordination between manufacturing, logistics, and providers. Furthermore, the anticipated cost associated with C>s may create unique challenges for payers.

OBJECTIVE: To understand the challenges payers face when evaluating C>s for coverage.

METHODS: A survey link was sent to members of Xcenda's Managed Care Network (MCN), a network of approximately 140 decision makers from managed care organizations (MCOs), pharmacy benefits management companies (PBMs), integrated delivery network (IDNs), specialty pharmacy providers (SPPs), and other health delivery organizations.

RESULTS: A total of 46 respondents completed the survey, representing MCOs (78%), PBMs (17%), IDNs, hospital systems (9%), and SPPs (4%). They represent organizations collectively managing close to 256 million lives. Majority of the respondents (83%) agree that no clear precedent has been established with how C>s are evaluated. Only 11% state that their organization is currently developing a separate process to evaluate C>s and another 63% recognize that there is a need to develop a process. Those with a process currently in development are all MCOs, 3 national and 2 regional plans collectively managing 25.5 million lives. Among 6 listed challenges, respondents rank the lack of long-term outcomes data and total cost of therapy as their top two most impeding challenges in providing coverage for C>s. Only 7% of respondents say that they have the necessary operational resources to monitor long-term outcomes associated with C>s while another 33% say that they have some but lack other resources to do so. Approximately a quarter of the respondents (28%) are currently evaluating a different approach to finance C>s.

CONCLUSIONS: C>s establish unique and unprecedented challenges for the payer. While only a few payer organizations are currently developing a separate process to evaluate C>s, a majority recognize the need to develop one in the future, especially given the development pipeline. Finding adequate resources and innovative financial solutions are initial first steps that payers may take to provide coverage of C>s for their members. Additionally, it will be imperative that manufacturer organizations help to address these critical challenges.

SPONSORSHIP: Xcenda.

U8 The Impact of Collaborative Pharmacy Care on Medication Adherence

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PROBLEM DESCRIPTION: Medication adherence continues to be an ongoing barrier to chronic disease state management. An estimated 20-30% of initial prescriptions are never filled, while up to 50% of patients do not continue to fill maintenance drugs as prescribed.

GOAL: The goal of this pilot program was to achieve a medication possession ratio (MPR) of ≥0.8 for more than 75% of eligible patients after the first fill of a new maintenance medication.

PROGRAM DESCRIPTION: This program capitalized on the collaboration between pharmacists at a regional health plan and a local primary care practice. The health plan pharmacist (HP) identified patients with a first fill of a chronic medication between 4/1/2016-2/28/17, including: anti-lipids, oral anticoagulants, antidepressants, maintenance inhalers, anti-hyperglycemics and anti-hypertensives. Exclusions were acute therapy <90 days, no refill, and change in site of care or inability to contact. The practice pharmacists (PP) attempted telephone counseling within 30 days of the first prescription claim. Barriers assessed for non-adherence included cost, medication access and low health literacy. The PP resolved issues within their scope of practice, documented clinical outcomes impacting adherence, and triaged to the prescriber for resolution as appropriate. Follow up calls were placed by the PP 90-120 days after the first fill. The HP and data analyst reviewed patient claims quarterly.

OBSERVATIONS: 96 patients were identified for outreach. 31 patients were excluded. Of 53 actionable patients counseled, 40 had an MPR≥0.8 (75.5%) at study end. 22 drug therapy issues were identified. The primary reason for medication discontinuation was adverse drug reaction (ADR). 3 patients were successfully switched to an alternative due to detection of an ADR. 2 interventions involving oral anticoagulant use were identified and intervention was considered urgent.

FINDINGS/RECOMMENDATIONS: Patients who experienced an ADR were more likely to discontinue treatment and counseling by the PP

did not appear to impact treatment duration when an ADR was present. Anti-depressants and statins were the most frequently discontinued medications. Future improvements may include creation of an algorithm for managing initial drug selection and ADR's, including a control population for comparing adherence rates; and expanding the population to also include members who are not new to therapy.

SPONSORSHIP: BlueShield of Northeastern New York.

U9 Effect of Intensive Utilization Management Compared to Exclusionary Formulary on Cost of Pharmacy Benefits

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BACKGROUND: Exclusionary formularies have been widely used for controlling pharmaceutical costs. However, utilizing an exclusionary formulary may have unintended consequences. Exploration of other effective ways to promote appropriate utilization of pharmaceutical care while containing costs is needed.

OBJECTIVE: To investigate the effect of intensive utilization management in comparison to an exclusionary formulary on the cost of pharmacy benefits.

METHODS: A cross-sectional study analyzed 2015-16 claims data of a pharmacy benefit management company, EmpiRx Health. The outcome variable was pharmaceutical costs measured by average wholesale price (AWP). The primary independent variable was the use of utilization management tools, including prior authorization (PA), quantity limits (QL) and tiering of specialty pharmaceuticals. Pharmaceuticals were categorized by Medispan drug groups. T-tests were used to test the difference in mean cost between claims of open formulary with intensive utilization management and those of an exclusionary formulary with minimum utilization management.

RESULTS: We analyzed 686,308 claims for 2015-16, among which 661,844 claims were for clients utilizing open formulary with intensive utilization management and 24,464 claims for clients utilizing an exclusionary formulary with minimum utilization management. The mean costs were $164.31 for claims using the open formulary with intensive utilization management and $201.34 for claims using an exclusionary formulary with minimum utilization management ($P<0.0001$). The mean costs were $1,658.15 for claims using PA and $156.12 for claims not using PA ($P<0.0001$), $546.15 for claims using QL and $158.50 for claims not using QL ($P<0.0001$), and $2,295.71 for claims with specialty pharmaceutical indicator and $150.70 for non-specialty claims ($P<0.0001$). Open formulary with intensive utilization management was most effective for psychotherapeutic and neurological agents ($1,188.20 for claims using the open formulary with intensitve utilization management vs. $3,240.11 for claims using an exclusionary formulary with minimum utilization management, $P<0.0001$).

CONCLUSIONS: An open formulary approach with intensive utilization management provides better cost containment and helps promote appropriate utilization in comparison to controlling utilization through an exclusionary formulary.

SPONSORSHIP: EmpiRx Health.

U10 Impact of Pharmacist Outreach on Beta Blocker Adherence After Myocardial Infarction

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PROBLEM DESCRIPTION: Early outpatient follow-up after acute myocardial infarction has been associated with higher rates of medication use. Despite such efforts, adherence to medication use remains an issue.

GOAL: To improve the Healthcare Effectiveness and Data Information Set (HEDIS) measure titled Persistence of Beta Blocker Therapy after a Heart Attack (PBH) in a commercial managed care health plan through pharmacist outbound calls.

PROGRAM DESCRIPTION: Hospital discharge data are reviewed weekly to identify members in a commercial health plan diagnosed with a heart attack (ICD-9 or ICD-10 codes). Pharmacy claims system is referenced to determine if a beta blocker is filled within 7 days of the discharge date. If a beta blocker is not filled, the primary care physician is notified via fax and asked to respond if a beta blocker is warranted. Members are tracked monthly to ensure medications are filled regularly. Members with 14 days or greater gap in a refill are contacted via phone to discuss medication adherence using motivational interviewing skills. Three attempts are made to reach a member, after the 3rd attempt, a letter may be mailed outlining the importance of medication adherence. Medication adherence is evaluated using the proportion of days covered during the 6 month follow-up post discharge.

OBSERVATIONS: From October 24, 2016 through June 19, 2017, a total of 78 plan members were identified with heart attack diagnosis codes (2 were excluded due to coding errors). A total of 14 patients did not have a beta blocker fill which resulted in a fax to the physician; only 3 responses were received indicating beta blocker was not initiated for various reasons. Fourteen patients received outbound calls due to delays in beta blocker fills; 5 (36%) were reached and 9 (64%) were never reached. The average proportion of days covered for patients who engaged in a phone call was 0.73 versus 0.43 for patients who were never reached.

FINDINGS/RECOMMENDATIONS: Although the number of members identified was small, engaging in a conversation with a pharmacist had a positive impact on medication adherence. Limitations of this endeavor include lack of hospital discharge notifications on PPO members to the health plan. Claims data were not used due to lag time in receiving claims. As a result, primarily HMO members were tracked and contacted for non-adherence.

SPONSORSHIP: None.

U11 Real-World Retention Patterns of Patients Treated with Innovator or Biosimilar Infliximab or Switched from Innovator to Biosimilar Infliximab in Germany

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BACKGROUND: Recent clinical studies that have compared the use of, and switching between, innovator infliximab (REMICADE) and its biosimilars (INFLECTRA and REMSIMA) have suggested similar safety and efficacy outcomes. However there is a lack of evidence demonstrating this similarity in the real world. Given low uptake of biosimilars in North America to date, we aimed to find a proxy country to evaluate the retention patterns of patients treated with innovator and biosimilar infliximab.

OBJECTIVE: To compare the 6-month post-switch retention and 12-month overall retention of infliximab and biosimilar infliximab in Germany.

METHODS: QuintilesIMS longitudinal health insurance prescription data from Germany was used to identify patients with an initial claim of infliximab (REMICADE, INFLECTRA or REMSIMA) between Feb

2015-Oct 2016 by any prescriber type. 12-month post-drug initiation and 6-month post innovator-to-biosimilar switch retention analyses were conducted. All patients must have had sufficient claims history and had > 2 claims of the drug within the analysis period. Retention was captured as the proportion of patients remaining on treatment at each respective time point, captured in 90-day increments.

RESULTS: 6,491 patients had an infliximab claim between Feb 2015-Oct 2016. Patients on the innovator (n = 3,697, 57%) and biosimilar (n = 2,794, 43%) groups were comparable with respect to age, gender, the physician prescriber and biologic naive status. After 6 months, 14.3% more patients who stayed on innovator infliximab remained on treatment compared to those who had switched from the innovator to a biosimilar ($P < 0.01$). At 12 months, 9.4% more patients treated with innovator infliximab remained on treatment compared to those who had initiated and continued a biosimilar ($P < 0.01$).

CONCLUSIONS: Significant differences were noted in real-world retention amongst overall patients treated with innovator or biosimilar versions of infliximab in Germany. Further investigation is needed to better understand these differences regarding impact of switching from reference drug to biosimilars.

SPONSORSHIP: Janssen Scientific Affairs.

U12 Review of Psychotropic Medication and Mental Health Service Use in Individuals in Foster Care Versus Nonfoster Care in a State Medicaid Population

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BACKGROUND: Previous literature has shown that individuals in foster care are more likely prescribed psychotropic medications than those not in foster care. However, lack of information regarding multi-class psychotropic utilization prompted the Oklahoma Department of Human Services, the Oklahoma Healthcare Authority, and the University of Oklahoma College of Pharmacy's Pharmacy Management Consultants to review use in the state's Medicaid's foster care population.

OBJECTIVE: Compare psychotropic medication utilization and mental health service use in individuals in foster care against those not in foster care across various socio-demographic factors. An additional objective is to assess concurrent psychotropic medication class use between the two populations.

METHODS: Paid prescription, outpatient, and inpatient claims for 2016 were extracted for 649,193 individuals up to 21 years old. This cross-sectional analysis compared descriptive statistics of 9,235 individuals in foster care to 639,868 individuals not in foster care in the Medicaid population. Subjects were defined as "poly-class" if they were taking at least 2 different psychotropic medication classes at the same time for at least 90 consecutive days during 2016. A logistic regression analyzed the odds of poly-class between the two groups across independent variables.

RESULTS: Overall, individuals in foster care were younger (mean: 6.4 years vs. 8.7, $P < 0.001$), less male (50.5% vs. 52.1%, $P = 0.003$), and receive a higher proportion of mental health prescription medications (22.4% vs. 10.6%, $P < 0.001$). Those in foster care had higher proportions of poly-pharmacy use across all mental health medication categories as well as a higher proportion of poly-class (9.2% vs. 1.9%, $P < 0.001$). Individuals in foster care receiving no psychotherapy had a higher odds of poly-class than individuals not in foster care receiving no psychotherapy (adjusted OR = 5.8, 95% CI: 5.2 to 6.5). Additionally, individuals in foster care receiving psychotherapy had higher odds of poly-class than individuals not in foster care receiving psychotherapy (adjusted OR = 2.2, 95% CI: 2.0 to 2.5).

CONCLUSIONS: In this Medicaid program, higher psychotropic poly-class is observed in individuals in foster care compared to the population not in foster care. Additionally, odds of poly-class use was higher for individuals in foster care not receiving psychotherapy. These findings will be used to guide additional projects in improving the quality of the foster care psychotropic medication use process.

SPONSORSHIP: CHIP Health Services Initiative.

U13 Making the Case to Increase the Percentage of Patients Eligible for Medication Therapy Management Programs to Improve Star Ratings

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PROBLEM DESCRIPTION: As noted in the 2013 Medicare Call Letter, health plans were expected to increase eligibility rates for medication therapy management (MTM) programs. The average enrollment at that time was 10-13%, a rate unchanged since 2006. In the 2014 Call Letter, CMS stated that high performing plans were using MTM programs to boost star ratings. This analysis evaluates the impact of MTM on star ratings as an argument for increasing the percentage of members eligible for the MTM program.

GOAL: Our goal is to determine if Part D sponsors can leverage MTM programs to improve four specific Part D star metrics: Medication Adherence for Diabetes Medications (Adh DM), Medication Adherence for Hypertension (Adh RAS), Medication Adherence for Cholesterol (Adh Statins), and Statin Use in Persons with Diabetes (SUPD).

PROGRAM DESCRIPTION: We pooled data from three Medicare health plans representing 262,986 members. The overall MTM enrollment was 5% of the population. We used MTM enrollment data and the year end stars data (as supplied by Acumen) for the four star metrics. We calculated the percentage of members meeting the numerator criteria (either adding a statin to drug regimens for diabetic patients or achieving an 80% proportion of days covered for the adherence rates). We compared rates for those enrolled in MTM to those not in the program. Using a Chi-square analysis, we determined if there was a statistically significant difference in rates.

OBSERVATIONS: For SUPD overall, 75% of diabetic members were on statins (n = 31,343/41,766). The rate for members in MTM was 86% (n = 6,183/7,158) compared to 73% (n = 25,160/34,608) in the non-MTM group ($P < 0.001$). For Adh DM overall, 81% of members were adherent (n = 34,141/42,333). Of these, MTM members demonstrated a rate of 88% (n = 4,534/5,167) compared to 80% (n = 29,607/37,166) in the non-MTM group ($P < 0.001$). For Adh RAS overall, the rate was 82% (n = 93,904/114,142). The rate for members in MTM was 85% (n = 7,864/9,207) compared to 82% (n = 86,040/104,935) in the non-MTM group ($P < 0.001$). For Adh Statins overall, the rate was 80% (n = 89,272/112,065). The rate for members in MTM was 84% (n = 8,568/10,195) compared to 79% (n = 80,704/101,870) in the non-MTM group ($P < 0.001$).

FINDINGS/RECOMMENDATIONS: Results from this analysis suggest that MTM programs have a significant impact on improving star rating performance; however, low enrollment in MTM limits the overall effect of the program. If a larger percentage of members were in MTM, higher rates for the star metrics could be achieved. Using the 2017 cut-points, pooled data from this analysis suggest that the plans could achieve 5-stars in the adherence metrics if most members were in MTM.

SPONSORSHIP: None.

U14 Impact of Pharmacist Intervention on Statin Use in Persons with Diabetes in a Medicare Advantage Population

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PROBLEM DESCRIPTION: The Centers for Medicare and Medicaid Services evaluates medication-related quality and assigns Part D Star Ratings to Medicare Plans. One performance measure is the Statin Use in Persons with Diabetes (SUPD) measure, which assesses the percentage of patients between 40 and 75 years old being dispensed a medication for diabetes who receive a statin medication. Cigna HealthCare of Arizona, a Medicare Advantage organization, is a staff model HMO. Its Cigna Medical Group (CMG) Sun City West Healthcare Center was at 70% for the SUPD measure in 2017 prior to any pharmacist interventions, and the estimated target for the 5-Star threshold is 80%.

GOAL: To describe and assess the effectiveness of pharmacist interventions on the percentage of Medicare Advantage Prescription Drug (MAPD) patients between 40 and 75 years old who have received two fills of diabetes medications and are on a statin medication.

PROGRAM DESCRIPTION: Patient-specific claims data were retrieved directly from the CMG Sun City West Healthcare Center's pharmacy operating system for all fills of diabetic medications in 2017 and exported to a Microsoft Excel worksheet. Prior to any interventions, the pharmacist spoke to the CMG primary care providers (PCPs) in person to review the recommendations, educate them about the SUPD measure, and make them aware that the pharmacist would be conducting outreach to patients who may be candidates for statin therapy. The pharmacist performed the appropriate interventions after conducting a chart review for each patient. Pharmacist interventions included calls to patients, calls to PCPs, and direct messages within the shared electronic health record to CMG PCPs.

OBSERVATIONS: There were 39 MAPD patients who had 2 fills of a diabetes medication and no prescription claim for a statin medication in 2017. Of these 39 MAPD patients, a statin medication was prescribed for 21 patients (54%) after pharmacist intervention. Following pharmacist intervention, the percentage of MAPD patients between 40 and 75 years old with 2 fills of a diabetes medication and on a statin medication increased from 70% to 86% of patients.

FINDINGS/RECOMMENDATIONS: Pharmacists may have a high impact on the initiation of a statin medication for patients with diabetes. Pharmacists can provide proper education for statin therapy to both patients and physicians and serve an important role in not only improving Star Ratings measures, but also providing clinically appropriate recommendations for statin therapy.

SPONSORSHIP: None.

U15 Comparing U.S. Payers and Hospital Providers: The Current Trend for Preapproval Information Requests to Support Formulary Decisions

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PROBLEM DESCRIPTION: Pre-approval information exchange between payers and manufacturers, advocated by AMCP and others, supports payer budget and formulary planning due to robust drug pipelines with promising yet costly treatments. Payers are now reviewing products 12-24 months before FDA approval and this trend is acknowledged with recent proposed legislation and FDA draft guidance. 2016 research indicated an increased need for earlier exchange of information between manufacturers and payers. Is the trend the same for hospital providers? The AMCP eDossier System (System) is a secure, web-based system within FormularyDecisions.com supporting the exchange of manufacturer information with payers and providers.

GOAL: To determine whether the payer trend for earlier product information also affects hospital providers involved in formulary decision making.

PROGRAM DESCRIPTION: In November 2016, registered System users participated in an online survey detailing their use of pre-approval information. A second identical survey was completed in June 2017 targeting hospital users of the System to compare the results of both surveys.

OBSERVATIONS: Late 2016, 172 System users indicated utilizing pre-approval information to support formulary decisions; of the 172, 79 self-identified as payers, 48 as hospital providers. In the 2017, an identical survey was repeated with hospital providers. All survey responses were grouped, payer and hospital, and compared. The respondent profile regarding annual requests for manufacturer information was similar in volume, with the majority making 1-5 requests (62% payers; 72% hospital providers) and a quarter of respondents made 6-10 requests. Both groups identified clinical and FDA pipeline information as 2 of the top 3 types of information used for pre-approval product reviews. Hospital providers differed using more curated information vs payers more manufacturer information. The ranking of requested manufacturer information types was similar between both groups: clinical, safety, therapeutic and health economic respectively. Most in both groups indicated manufacturer response within 2 weeks (59% payers; 77% hospital providers). The Format v4.0 update facilitated an easier exchange of pre-approval information for both groups (45% payers; 36% hospital providers).

FINDINGS/RECOMMENDATIONS: The research indicates that payers and hospital providers have similar trends toward earlier product information requirements. The importance of manufacturer provided information was indicated by both groups. There appears to be an opportunity to increase manufacturer responsiveness, if identified barriers could be overcome.

SPONSORSHIP: Dymaxium.

U16 Establishment of a Specialty Pharmacy Patient Advisory Board to Assess Patients' Perspective on Barriers to Specialty Medication Access and Use

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PROBLEM DESCRIPTION: Specialty medications have barriers to access and use, such as out-of-pocket costs, inadequate insurance coverage, possible adverse effects of the drug, complicated enrollment and limited distribution processes. The impact of these barriers on providers and the healthcare system is well known; however, patient perception of these barriers is less clear.

GOAL: The goal of this project was to understand the patient's perspective on barriers to access and use of specialty medications and to develop patient-friendly ideas for service improvement.

PROGRAM DESCRIPTION: University of Illinois Hospital and Health Sciences System (UI Health) has an accredited Specialty Pharmacy Service (SPS) for patients with chronic disease states including cancer, rheumatoid arthritis, hepatitis C, and multiple sclerosis. SPS established a Patient Advisory Board (PAB) that consisted of UI Health patients who were prescribed a specialty medication in 2016 and 2017. They were either SPS patients or received their specialty medication elsewhere due to manufacturer limited distribution

requirements, insurance network restrictions or choice. A total of 17 patients attended at least one of the three meetings held between June 2016 and April 2017. The meetings were moderated in-person discussions that focused on access pain points including lack of knowledge, communication with providers and the specialty pharmacy, medication affordability, accessibility and distribution, insurance coverage. Graphic scribing was used for the first session to capture the essence of the members and their feelings. A waiver of consent was obtained from all participants.

OBSERVATIONS: Among members of the PAB, the main concern was inability or frustration with navigating insurance processes. Most feared changing insurance due to loss of coverage or change in formulary, restrictions due to step therapy and copay changes warranting gaps in care. The members expressed desire for improved continuity of care with lab reminders, nutrition and wellness programs, patient friendly disease state updates, and tips on managing medication side effects. There is an increased interest in integrating technology to communicate with pharmacists.

FINDINGS/RECOMMENDATIONS: Based on the PAB discussions, UI-SPS is working on measures to address patient's perceived barriers to access and use, improve patient satisfaction and ensure continuity of care with specialty medications through providing educational newsletters, comprehensive welcome packets, and complimentary services. These findings can set the foundation for quality improvement projects, patient advocacy, and other lobbying efforts.

SPONSORSHIP: None.

U17 State Medicaid Performance on CDC Guidelines: Implications for Drug Utilization Management

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BACKGROUND: In March 2016, the CDC released Guidelines for Prescribing Opioids for Chronic Pain. The Office of Inspector General's 2016 Work Plan included a focus on how Medicaid's drug utilization review (DUR) programs should address opioid misuse. Medicaid programs and other health plans are taking actions to prevent opioid misuse and to treat beneficiaries with addiction problems.

OBJECTIVE: The objective was to examine congruence of current prescribing patterns and the CDC recommendations for prescribing opioids and to identify potential changes to the Mississippi Medicaid Universal Preferred Drug List for fee-for-service (FFS) and managed care organizations (MCOs).

METHODS: A retrospective analysis was conducted using FFS and MCO prescription and medical claims for calendar year 2016. Beneficiaries with cancer diagnoses were excluded. Opioid prescriptions (RXs) for those with no prior prescriptions within 180 days were classified as "new starts."

RESULTS: Examination of five CDC recommendations yielded the following results and need for action. Of 41,369 beneficiaries having new starts, 145 (0.3%) started on long-acting (LA) opioids. An electronic edit (EE) was recommended requiring manual prior authorization (PA) for new starts using LA products. New starts had initial fills for >7 days supply in 10,142 (21.2%) of beneficiaries. An EE was recommended limiting new starts to 2 initial prescriptions for ≤7 days supply. 14,680 (4.1%) opioid prescriptions were filled for ≥90 morphine equivalent daily dosing (MEDD) and 8,425 (2.4%) were filled for ≥ 120 MEDD. Recommendations were made for an EE requiring manual PA for ≥90 MEDD and educational intervention for providers. During 2016, 3,940 (3.3%) of beneficiaries taking opioids had concomitant use with benzodiazepines. These concomitant RXs were prescribed by the same provider 78% of the time and filled in the same pharmacy 92% of the time. An EE is being implemented to reject new starts for benzodiazepines resulting in concomitant use. An educational intervention addressing concomitant use is underway. Utilization of medication-assisted treatment with buprenorphine/naloxone has increased. After review of current utilization guidelines for buprenorphine/naloxone medications, PA criteria were modified to increase access.

CONCLUSIONS: Congruence with the CDC Guidelines varied by recommendation. Several areas were identified for drug utilization management actions. It is important that health plans evaluate the effect of the CDC recommendations and take actions to address the opioid abuse problem in the United States.

SPONSORSHIP: Mississippi Division of Medicaid.

U18 Current Management of Specialty Drugs, Specialty Pharmacies, and Biosimilar Drugs

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BACKGROUND: Specialty medicines in 2016 were responsible for 42.9% of net spending and 39.6% on an invoice-price basis. Biologic drugs are a large portion of specialty spending and health plans are expected to adjust their formularies to maximize expected savings from biosimilars.

OBJECTIVE: A better understanding of health plan management of specialty pharmacy (SP), SP products, and biosimilars of SP products.

METHODS: Online survey sent to 459 U.S. medical+pharmacy directors (MDs+PDs) on: advisor+plan information; specialty pharmacies and specialty pharmaceuticals, expected biosimilar coverage, restrictions, and copays and to compare current results with prior surveys.

RESULTS: The survey was completed by 52 MDs+PDs (11.3%): 55.8% were MDs and worked for: health plans/IDNs/PPOs/IPAs = 57.7%; PBMs = 9.6%; Government = 3.8%; the remainder consultants. Plans were National = 41.9%; Regional = 34.9%; or Local = 23.3%. 51% restrict Specialty Providers (SPs). SPs were: PBM-owned 45.7%; 34.8% owned by the health plan; 17.4% independent; 10.9% hospital/IDN-owned. 65.9% of plans restricted SPs to those under contract; 6.8% only restricted SPs available through multiple SPs; 6.8% allowed any SP handling the agent. Specialty product copays continue to move from fixed to percentage with more plans using group+benefit design to determine the copay. Plans covered clinician administered products under the medical benefit (MB = 15.2%, previously 64.3%); under the pharmacy benefit (PB = 67.4%, previously 5.4%); the remainder varied based on price and plan design and 89.1% do not expect this to change. Biosimilar use is expected for all reference product indications (59.5%), while 31.0% will restrict to their approved indications (31.0%). Plans expect biosimilar copays to be indication based (9.5%), discounted off the innovator (45.2%); to vary based on the approval timing (33.3%) or be the only product available (21.4%). Member and provider biosimilar education will be provided through: different copays = 68.3%; prescriber mailings = 63.4%; patient mailings = 53.7%; prescriber calls = 39.0%; and patient calls = 19.5%. Biosimilars savings are expected to be: < 10% in 2017 (52.4%); 60.5% expect 10-20% by 2020; and 61.9% expect > 20% by 2025.

CONCLUSIONS: Costs associated with specialty pharmacies/pharmacy products have shifted and are expected to grow and require

appropriate coverage. The switch from the medical benefit to the pharmacy benefit for oral biologics and self-injected agents represents a significant change as SP management has grown. Biosimilars are expected to provide some cost growth relief but only over after the introduction of more than 2 competitive biosimilars.

SPONSORSHIP: TPG-National Payor Roundtable.

U19 Evaluation of an Opioid Management Program in a Medicaid Managed Care Organization

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Amida Care

BACKGROUND: Amida Care is a Medicaid Special Needs Health Plan for individuals living with HIV/AIDS in New York City. Historically, Amida Care had no restrictions or utilization management parameters in place for members receiving opioids. Thus, our opioid utilization closely reflected the high utilization trends of the United States opioid epidemic. In order to ensure safe and appropriate opioid utilization and mitigate the use of high doses, we developed a multi-phasic Chronic Opioid Program to address opioid use in non-cancer patients. The first phase, implemented on June 1, 2016, addressed the formulary and included Quantity Limits (QL) on all opioids. To minimize disruption we chose to implement a QL for each opioid medication at 200 Morphine Equivalents and grandfathered members who were above the QL at their current dose. Due to the high volume of methadone use and its unsafe pharmacokinetic properties, we chose not to grandfather high methadone doses, to monitor methadone more closely and require a dose tapering plan for all members who were above the QL. Phase II of the program was implemented on October 1, 2016 and included a Prior Authorization for all new starts of methadone and NYS mandates limiting initial opioid prescribing to 7 days supply for acute pain and limiting the number of opioid prescriptions to four prescriptions per 30 days. Phase III set a high dose limit at 200 mg/day of total daily morphine equivalents, implemented July 2017, which is not included in this analysis.

OBJECTIVE: To evaluate the impact of Amida Care's opioid utilization management program on total opioid utilization.

METHODS: An observational retrospective evaluation, this study aims to describe the impact of pharmacy benefit driven interventions (Phase I and Phase II) on opioid utilization for members who were taking chronic opioids for non-cancer pain.

RESULTS: Three months prior to implementation (3/1/2016 to 5/31/2016) was compared to end of the study period (3/1/2017 to 5/31/2017), the proportion of opioid utilizers declined by 10% and the overall total daily dose (in morphine equivalents) of all opioids declined by 40%. Methadone utilization decreased by 60%. More detailed analysis, including statistical significance, will be included in poster.

CONCLUSIONS: This analysis demonstrates that a managed care pharmacy driven initiative including formulary restrictions can decrease opioid utilization and potentially mitigate the misuse and abuse of prescription opioids.

SPONSORSHIP: Amida Care.

U20 Implementing Pharmacogenomic Consultation into Prescribing

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PROBLEM DESCRIPTION: While the science of pharmacogenomics (PGx) is rapidly advancing, many health care professionals do not feel adequately informed to interpret PGx data and make associated clinical recommendations. Much debate also exists as to which health care setting(s) is/are most appropriate for PGx testing and associated pharmacotherapy optimization.

GOAL: To pilot a pharmacist PGx consult service to provide clinical decision support for drug therapy optimization.

PROGRAM DESCRIPTION: Pharmacists received home study and live training to support the application of PGx data to pharmacotherapy. Prescribers identified patients with uncontrolled mental health needs, and a cheek swab was obtained for PGx analysis. Along with the cheek swab sample, a medication list and list of pertinent diagnoses was provided to the PGx testing lab. Via a web-based portal, information from the prescriber and PGx data from the lab was provided to a pharmacist. A patient-specific consult report that included recommended pharmacotherapy interventions in a summarized format was generated for the prescriber and shared via the web-based portal.

OBSERVATIONS: Following training specific to PGx, pharmacists were able to customize a patient-specific PGx consult report to ordering prescribers. The web-based portal allowed for secure electronic file sharing between the PGx lab, the pharmacist, and the prescriber. Variation in process for report generation was observed among different pharmacists, so a more standardized process was developed for reporting recommendations. Further process revisions also occurred, notably to increase the baseline data requests from the ordering prescriber to include a complete list of current medications and health conditions, as well as reason(s) for ordering the PGx test. This data was used for further customization of clinical recommendations.

FINDINGS/RECOMMENDATIONS: Pharmacists were well trained in pharmacotherapy at baseline and were able to begin applying PGx data through consult reports following training. A modest investment in pharmacist training and secure electronic file sharing allowed for rapid uptake of a PGx consult service. Future research is warranted to optimize workflow for efficiency and utility, and to better assess perceptions of pharmacists and prescribers in the PGx consult service.

SPONSORSHIP: Private gift to the Western Michigan University Homer Stryker MD School of Medicine PGx Reporting. Online portal provided by Genemarkers.

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